

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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MEMORANDUM OPINION

Dated: March 10, 2004
Wilmington, Delaware

John L. Robinson
ROBINSON, Chief Judge

I. INTRODUCTION

On July 25, 2001, plaintiff Arthrocare Corporation ("Arthrocare") filed this action against defendant Smith & Nephew, Inc. ("Smith & Nephew") alleging willful direct, contributory, and inducing infringement of certain claims of U.S. Patent Nos. 5,697,536 (the "'536 patent"), 5,697,882 (the "'882 patent") and 6,224,592 (the "'592 patent"). (D.I. 1) Smith & Nephew answered the complaint on September 13, 2001 denying the infringement allegations and asserting five affirmative defenses including noninfringement, invalidity, misuse, unenforceability based upon inequitable conduct, and unclean hands. (Id.) Smith & Nephew also asserted counterclaims for a declaratory judgment that the patents in suit are invalid and not infringed by any act of Smith & Nephew and that the '592 patent is unenforceable due to inequitable conduct. (D.I. 10) On September 26, 2001, Arthrocare denied Smith & Nephew's counterclaims. (D.I. 20) With the court's permission, Smith & Nephew amended their answer on November 27, 2002 to add counterclaims for antitrust violations under 15 U.S.C. § 1 of the Sherman Act. (D.I. 219)

ArthroCare is organized under the laws of the State of Delaware with its principal place of business in California. (D.I. 1 at ¶2) Smith & Nephew is also organized under the laws of State of Delaware with its principal place of business in

Massachusetts. (Id. at ¶3) The court has jurisdiction over this case pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201(a).

The court separated the issues raised by the parties into two phases, the first phase to include the issues of infringement, validity, and inequitable conduct and the second phase to include the issues of damages, willfulness, and antitrust counterclaims. From April 30, 2003 through May 9, 2003, the parties tried the issues of infringement and invalidity before a jury. The court ruled on May 12, 2003 that the parties could submit their inequitable conduct cases on the briefs limited to the record created at trial. (See D.I. 418 at 1071-02) Currently before the court are the parties' post-trial motions on the issues of infringement, invalidity, and inequitable conduct.¹ (D.I. 424, 427, 432, 437, 455, 458)

¹Smith & Nephew challenges every decision made by the jury in rendering its verdict and numerous evidentiary decisions rendered by the court during the trial.

Smith & Nephew filed a motion to modify the protective order to permit key Smith & Nephew business personnel to view specific terms of Arthrocare's settlement agreement with Ethicon in an attempt to facilitate settlement discussions between the parties. (D.I. 432) Because there are no active settlement discussions currently ongoing, the court denies this motion as moot.

Smith & Nephew also filed a motion for judgment as a matter of law on the issues of (1) infringement under the doctrine of equivalents; (2) infringement of claim 54 of the '882 patent by non-suction models of the Saphyre probe; and (3) direct infringement of the '592 and '882 patents. (See D.I. 459 at 5, 6, and 19) None of these issues were presented to the jury. Likewise, neither the jury instructions nor the special verdict form asked the jury to decide these issues. Accordingly, the court finds that judgment as a matter of law is improper under the federal rules and will not entertain these motions.

II. BACKGROUND

A. Electrosurgery In General

The patents in suit generally relate to electrosurgery and to surgical devices and methods that employ high frequency voltage to cut and ablate tissue. These devices are of either a monopolar or a bipolar nature. A monopolar device, as the name suggests, consists of only a single electrode. It directs an electric current from the exposed or active electrode through a patient's body to a return electrode externally attached to the patient's body. In contrast, a bipolar device consists of two electrodes. An active electrode in contact with the patient's tissue transmits an electric current through the patient's tissue to a return electrode also in contact with the patient's tissue. When using either type of device, the target region must be treated with isotonic saline to maintain an isotonic environment around the tissue and to keep the area in clear view.

Electrosurgical techniques are advantageous because they reduce patient bleeding and the trauma associated with operations involving cutting. At the same time, a diverse range of risks may be implicated. With monopolar devices, electric current may flow in undefined paths through a patient's body. Also, high voltages typically must be applied to generate a current suitable for cutting or ablation using either monopolar or bipolar

devices. Such high voltage may damage or destroy surrounding tissue.

B. The Patents In Suit

The patents in suit involve improvements over the monopolar and bipolar devices of the prior art. Specifically, the '536 patent claims an electrosurgical system comprising an electrosurgical probe, a return electrode, and a fluid delivery element. The '592 and '882 patents, in turn, claim methods of using the system disclosed in the '536 patent to apply electrical energy adjacent to the target tissue without submerging the target tissue in an electrically conducting irrigant. Each patent will be considered in further detail as relevant to the parties' post-trial motions.

1. The '536 Patent

The '536 patent, entitled "System and Method for Electrosurgical Cutting and Ablation," was issued on December 16, 1997 with Philip E. Eggers and Hira V. Thapliyal as inventors. It was originally filed on November 18, 1996. The '536 patent traces priority to the now abandoned U.S. Application No. 817,575. It was granted with sixty-four claims on December 16, 1997. On December 23, 1999, a third party filed a request for an ex parte reexamination based solely upon prior art. The United States Patent and Trademark Office ("PTO") granted this request

and, after reexam, issued a "Notice of Intent to Issue an Ex Parte Reexamination Certificate" as to all original claims.

Claims 46, 47, and 56 are presently asserted and are apparatus type claims. Claims 46 and 56 depend from claim 45. Claim 47 depends from claim 46. These claims read as follows:

45. An electrosurgical system for applying electrical energy to a target site on a structure within or on a patient's body, the system comprising:
 - a high frequency power supply;
 - an electrosurgical probe comprising a shaft having a proximal end and a distal end, and a connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply;
 - a return electrode electrically coupled to the electrosurgical power supply; and
 - an electrically conducting fluid supply for directing electrically conducting fluid to the target site such that the electrically conducting fluid generates a current flow path between the return electrode and the electrode terminal.
46. An electrosurgical system as in claim 45, wherein the return electrode forms a portion of the shaft of the electrosurgical probe.
47. An electrosurgical system as in claim 46 further including an insulating member circumscribing the return electrode, the return electrode being sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode and the patient's tissue.
56. The electrosurgical system of claim 45 wherein the target site is selected from the group consisting essentially of the abdominal cavity, thoracic cavity, knee, shoulder, hip, hand, foot, elbow, mouth, spine, ear, nose, throat, epidermis and dermis of the patient's body.

('536 patent, col. 18 at ll. 13-36; col. 19 at ll. 11-15)

The court construed disputed terms of the '536 patent to ascertain both their meaning and scope. (D.I. 353) The most significant constructions for the purposes of resolving the parties' post-trial motions are as follows:

1. The term "electrosurgical system" shall be given its "ordinary definition" and construed to mean "an assemblage or combination of things or parts forming a unitary whole."
2. The term "return electrode" shall be construed to mean "an electrode having a larger area of contact than an active electrode, thus affording a lower current density."
3. The term "connector" shall be construed to mean "a structure that electrically links the electrode terminal to the high frequency power supply."
4. The phrases "spacing a return electrode away from the body structure" and "the return electrode is not in contact with the body structure" shall be construed to mean that the return electrode is not to contact the body at all during the performance of the claimed method.²
5. The term "electrically conducting fluid" and "electrically conductive fluid" shall be construed to mean "any fluid that facilitates the passage of electrical current."

²The court supplemented this construction in its jury instructions with the following addition: "The claimed method does not contain any time limitations. Thus, the claimed method is performed when each of the three steps has been completed." (D.I. 418 at 1718)

2. The '882 Patent

The '882 patent, entitled "System and Method for Electrosurgical Cutting and Ablation," was issued on December 16, 1997 with Philip E. Eggers and Hira V. Thapliyal as inventors. It was originally filed on November 22, 1995 and traces priority to the same original application as the '536 patent, namely U.S. Application No. 817,575. The '882 patent was granted with fifty-six claims on December 16, 1997. Claims 13, 17, and 54 are presently asserted. All are method type claims. Claims 13 and 17 depend from claim 1 and claim 54 depends from both claim 1 and claim 28. These claims recite:

1. A method for applying energy to a target site on a patient body structure comprising:
providing an electrode terminal and a return electrode, electrically coupled to a high frequency voltage source;
positioning the active electrode in close proximity to the target site in the presence of an electrically conducting fluid; and applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.
13. The method of claim 1 wherein at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum.
17. The method of claim 1 wherein the high frequency voltage is at least 200 volts peak to peak.
28. A method for applying energy to a target site on a patient body structure comprising:

providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source;
positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to impart sufficient energy into the target site to ablate the body structure without causing substantial tissue necrosis below the surface of the body structure underlying the ablated body structure.

54. The method of claims 1 and 28 further comprising evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal.

('882 patent, col. 24 at ll. 5-18; 54-56, 64-65; col. 25 at ll. 38-51; col. 28 at ll. 9-10)

Pursuant to multiple certificates of correction granted after the '882 patent originally issued, the language recited in several claims was corrected. Of interest to the parties' post-trial motions, claim 1 was corrected on April 7, 1998. Claim 54 was corrected on May 2, 1998. For sake of clarity, the corrected language is shown below in bold with the original language in parentheses.

1. A method for applying energy to a target site on a patient body structure comprising:
providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source;
positioning the [active] electrode **terminal** in close proximity to the target site in the presence of an electrically conducting [terminal] **fluid**; and applying a high frequency voltage between the electrode terminal and the return electrode,

the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

54. The method of claims [1 and 28] **23 or 48** further comprising evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal.

('882 patent, Certificates of Correction dated August 25, 1998, April 7, 1998, and May 2, 2001) (emphasis added)

3. The '592 Patent

The '592 patent, entitled "Systems and Methods for Electrosurgical Tissue Treatment in Conductive Fluid," was issued on May 1, 2001 with Philip E. Eggers and Hira V. Thapliyal as inventors. It was originally filed on July 27, 1998 and traces priority to the '882 patent. Specifically, the '592 patent is a division of U.S. Patent No. 5,871,469, which is a division of the '882 patent. The '592 patent was granted with forty-three claims on May 1, 2001. Claims 1, 3, 4, 11, 21, 23, 26, 27, 32, and 42 are presently asserted and are all method type claims. Claims 3, 4, 11, and 21 depend from claim 1. Claim 26, 27, 32, and 42 depend from claim 23. These claims read as follows:

1. A method for applying electrical energy to a target site on a body structure on or within a patient's body, the method comprising:
positioning an electrode terminal into at least close proximity with the target site in the presence of an electrically conductive fluid;
positioning a return electrode within the electrically conductive fluid such that the return electrode is not in contact with the body structure to generate

a current flow path between the electrode terminal and the return electrode; and applying a high frequency voltage difference between the electrode terminal and the return electrode such that an electrical current flows from the electrode terminal, through the region of the target site, and to the return electrode through the current flow path.

3. The method of claim 1 further comprising immersing the target site within a volume of the electrically conductive fluid and positioning the return electrode within the volume of electrically conductive fluid to generate the current flow path between the electrode terminal and the return electrode.
4. The method of claim 1 further comprising delivering the electrically conductive fluid to the target site.
11. The method of claim 1 wherein the electrically conductive fluid comprises isotonic saline.
21. The method of claim 1 wherein the voltage is in the range from 500 to 1400 volts peak to peak.
23. A method for applying electrical energy to a target site on a body structure on or within a patient's body, the method comprising: contacting an active electrode with the body structure in the presence of an electrically conductive fluid; spacing a return electrode away from the body structure in the presence of the electrically conductive fluid; and applying a high frequency voltage difference between the active electrode and the return electrode such that an electrical current flows from the active electrode, through the electrically conductive fluid, and to the return electrode.
26. The method of claim 23 further comprising immersing the target site within a volume of the electrically conductive fluid and positioning the return electrode within the volume of electrically conductive fluid to generate a current flow path

between the active electrode and the return electrode.

27. The method of claim 23 further comprising delivering the electrically conductive fluid to the target site.
32. The method of claim 23 wherein the electrically conductive fluid comprises isotonic saline.
42. The method of claim 23 wherein the voltage is in the range from 500 to 1400 volts peak to peak.

('592 patent, col. 24 at ll. 6-21; 36-32; 64-65; col. 25 at ll. 36-37, 43-54, 61-67; col. 26 at ll. 20-21, 59-60)

The court construed disputed terms of the '592 patent to ascertain both their meaning and scope. (D.I. 353) The most significant constructions for the purposes of resolving the parties' post-trial motions are as follows:

1. The phrase "spacing a return electrode away from the body structure" and "the return electrode is not in contact with the body structure" means that the return electrode is not to contact the body at all during the performance of the claimed method.³
2. The term "electrically conducting fluid" and "electrically conductive fluid" shall be construed to mean "any fluid that facilitates the passage of electrical current."
3. The term "return electrode" shall be construed to mean "an electrode having a larger area of contact than an active electrode, thus affording a lower current density."

³The court supplemented this construction in its jury instructions. The court added the following: "The claimed method does not contain any time limitations. Thus, the claimed method is performed when each of the three steps has been completed." (D.I. 418 at 1718)

C. The Accused Products

Smith & Nephew presently manufactures and sells the Saphyre bipolar ablation probe ("Saphyre") and the ElectroBlade Resector ("ElectroBlade") for use in arthroscopic procedures. These products entered the market in 2002. It also previously manufactured and sold the Dyonics Control RF System ("Control RF") for use in arthroscopic procedures, but discontinued this product from the market in early 2002. (D.I. 436 at 3)

The Saphyre product consists of a stainless steel shaft with a plastic handle and a single large area active electrode at the far or "distal" end of the "shaft." (D.I. 400 at 3) The inner and outer surfaces of the Saphyre shaft are covered with an insulating coating, except at the distal tip where the active electrode is located. (Id.) A single return electrode clip is attached on top of this insulated shaft. (Id.) The return electrode and insulated shaft are covered with another insulating layer, except for a window located over the return electrode clip near the distal end of the shaft. (Id.) The Saphyre probe is connected to the Smith & Nephew Vulcan Generator. (Id. at 4)

The ElectroBlade probe consists of a stainless steel inner tube (i.e., inner blade) and a hollow stainless steel shaft (i.e., outer blade). (Id.) The inner blade slides into the shaft hollow and includes an opening near its distal end. The

inner blade rotates within the shaft when connected to a motor drive unit. (Id.) When it passes the edge of the opening in the shaft during rotation, a shearing action results. (Id. at 5) This shearing action serves to resect, or cut, target tissue. In addition to resecting tissue, the inner blade also acts as the active electrode when coagulation power is applied to the probe. (Id.) The return electrode is another hollow, stainless steel tube that runs from a point close to the opening in the shaft to a point in the handle. (Id.) The return electrode is covered with an insulating layer, except for an exposed section near the distal end of the shaft. The ElectroBlade probe does not contain a fluid delivery system. Instead, a separate instrument delivers fluid to the target tissue during an arthroscopic procedure. (Id. at 4) The ElectroBlade probe is connected to the Valleylab Force FX Generator. (Id. at 5)

Before being discontinued, the Control RF probe consisted of a stainless steel shaft in a plastic handle with a single active electrode at the far end. (Id. at 6) A return electrode was located near the active electrode at the far end of the shaft. The majority of the shaft was covered with an insulating material, except in the region of the active and return electrodes. (Id.) The Control RF probe did not contain a fluid delivery system; instead, a separate instrument pumped fluid during an arthroscopic surgery to the target tissue. (Id.) The

Control RF probe was connected to a Valleylab Force FX Generator via a Dyonics Control RF Generator Adaptor. (Id.)

D. The Alleged Prior Art

Throughout the course of the trial, Smith & Nephew introduced numerous documents in an attempt to establish that the patents in suit were invalid in light of prior art references.⁴ These references include four patents and two journal articles as follows: (1) U.S. Patent No. 4,116,198 (the "'198 patent"); (2) U.S. Patent No. 4,381,007 (the "'007 patent"); (3) U.S. Patent No. 4,674,499 (the "'499 patent"); (4) U.S. Patent No. 5,122,138 (the "'138 patent"); (5) "Vaporization of Atherosclerotic Plaques by Spark Erosion," 5 Journal of the American College of Cardiology, No. 6 at 1382-6 (1985) written by Cornelis J. Slager, et. al. (the "Slager article"); and (6) "Uber ein Instrument zur leckstromfreien transurethralen Resektion," (translated as "An Instrument for Transurethral Resection Without Leakage of Currents"), 24 Acta Medico Technica, No. 4 at 129-134 (1976) written by Von E. Elsasser and Eberhard. Roos (the "Elsasser/Roos article"). The '007 and '499 patents were cited to the PTO during the prosecution of the '536 and '882 patents. (See '536 patent cover; '882 patent cover) The Elsasser/Roos article was also cited during the prosecution of the '536 patent, and the

⁴The parties did not dispute that the documents introduced at trial by Smith & Nephew qualified as prior art in that they were available prior to the filing dates of the patents in suit.

'198 patent was cited during the reexamination of the '536 patent. (See '198 patent cover; '198 patent reexamination certificate)

The '198 patent, entitled "Electro-Surgical Device," is the most contentious item of prior art raised in the litigation at bar. Eberhard Roos is named as the sole inventor on this patent. In general, it relates to a bipolar electrosurgical device that may be passed through an endoscope. The device consists of a treatment electrode, a neutral electrode, a cable means to connect the treatment electrode to one pole of a high-frequency generator, another means for connecting the neutral electrode to the other pole of the high-frequency generator, and a channel for directing washing liquid to the treatment site. ('198 patent, col. 7 at ll. 45-61) The '198 invention is particularly directed toward electrosurgical operations on the filled bladder. (Id., col. 1 at ll. 18-21) Claim 1 of this patent recites:

1. In combination, an endoscope having an endoscope body of substantially tubular shape, an electro-surgical device comprising a treatment electrode projecting at one end from said endoscope body and a neutral electrode arranged adjacent said treatment electrode, insulated cable means for connecting said treatment electrode to one pole of a high-frequency generator, and means for connecting said neutral electrode to the other pole of a high-frequency generator, said endoscope body having an insulating projection extending over a portion of the periphery of said endoscope body at said one end and having a front edge, said neutral electrode being located within said endoscope body and spaced a distinct distance inwardly from said front edge, **a space being**

formed between said treatment electrode and said neutral electrode which is adapted to be filled with liquid to provide electrical conductance between said electrodes.

(Id., col. 7 at ll. 45-62) (emphasis added)

The '007 patent is entitled, "Multipolar Corneal-Shaping Electrode with Flexible Removable Skirt," and names James D. Doss as the sole inventor. This patent is directed toward a multipolar probe that employs radiofrequency electrical current to heat and thereby induce reshaping of the cornea in mammals. ('007 patent, col. 1 at ll. 10-13) The probe employs a plurality of electrode means that may be connected to the terminal of a radio-frequency source. (Id., col. 6 at ll. 60-61)

The '499 patent is entitled, "Coaxial Bipolar Probe," and names David S.C. Pao as the sole inventor. It discloses an electrosurgical bipolar electrode probe for use in ophthalmic, electrocautery, and electrocoagulation operations. ('499 patent, col. 1 at ll. 15-18)

The '138 patent is entitled, "Tissue Vaporizing Accessory and Method for an Endoscope," and names Kim H. Manwaring as the sole inventor. This patent is directed toward radio frequency energized endoscopic tissue dissection, vaporization, and coagulation devices designed for use in conjunction with an endoscope. ('138 patent, col. 1 at ll. 7-9; col. 2 at ll. 5-8) These devices may utilize a monopolar RF generator.

The Elsasser/Roos article essentially describes using one of the bipolar electrosurgery devices described in the '198 patent in thirty-two surgeries. In the summary section, this article states that "[t]he high-frequency current . . . flows directly from the active cutting electrode, **through the tissue to be cut and the irrigation liquid**, to the annular neutral electrode at the proximal end of the resectoscope shaft." (DTX 59-B at 7) (emphasis added) The Slager article describes the in vitro vaporization of fibrous and lipid plaques from segments of atherosclerotic human aortas using an electrical spark generator. (DTX 65)

E. The Arthrocare Corp. v. Ethicon, Inc. Decision

Arthrocare filed suit against Ethicon, Inc., Mitek Surgical Products, Inc., and Gynecare, Inc. in the Northern District of California on February 13, 1998, alleging infringement of eight claims in four patents. (Arthrocare Corp. v. Ethicon, Inc., No. C-98-0609 WHO (N.D. Cal. Dec. 1, 1998); D.I. 321, ex. A at 1) The claims at issue included: (1) claims 40 and 44 of U.S. Patent No. 5,697,909 (the "'909 patent"); (2) claim 45 of the '536 patent; (3) claim 101 of U.S. Patent No. 5,697, 281 (the "'281 patent"); and (4) claims 1, 26, 28, and 32 of the '882 patent. (Id. at 2) The case was assigned to Senior Judge William H. Orrick.

On March 10, 1998, Arthrocare moved for a preliminary injunction against Ethicon and Mitek to enjoin the two from making, using, importing, selling, or offering for sale an electrosurgery system marketed and sold under the VAPR System name. (Id.) Judge Orrick issued a memorandum decision on December 1, 1998 denying Arthrocare's preliminary injunction motion. (Id. at 33) Judge Orrick found substantial questions as to whether: (1) claims 40 and 44 of the '909 patent and claims 26 and 28 of the '882 patent are invalid for obviousness in light of the '198 patent and Elsasser/Roos article; (2) claim 45 of the '536 patent and claim 101 of the '281 patent are invalid for anticipation and obviousness in light of the '198 patent and Elsasser/Roos article; and (3) claims 1 and 32 of the '882 patent are invalid for lack of enablement. (Id.) The parties settled the litigation in June 1999 prior to trial.

F. Procedural History

In March 2003, the parties filed multiple motions for partial summary judgment. The court heard oral argument regarding these motions on April 1, 2003 and issued a memorandum opinion and order on April 9, 2003. (D.I. 352) The court denied Arthrocare's motions for partial summary judgment of infringement of the asserted claims of the '882 patent and claim 1 of the '592 patent, denied Smith & Nephew's motion for summary judgment of noninfringement of the asserted claims of the '882, '592, and

'536 patents, denied Arthrocare's motion for partial summary judgment that the patents in suit are not invalid due to obviousness based on an on-sale bar or public use, denied Smith & Nephew's motion for summary judgment of invalidity based upon prior art, and denied Smith & Nephew's motion for partial summary judgment of nonenablement, indefiniteness, and lack of written description. (Id.)

During the April 1, 2003 oral argument, the court also heard the parties' positions with respect to the disputed claim language of the patents in suit in accordance with Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996). The court issued a claim construction memorandum order on April 9, 2003. (D.I. 353)

G. The Trial

On April 30, 2003 through May 12, 2003, the parties tried their claims to a jury. The jury found by a preponderance of the evidence that Smith & Nephew directly infringed, induced infringement, and contributed to the infringement of claims 46, 47, and 56 of the '536 patent with its Saphyre, ElectroBlade, and Control RF products. (D.I. 405) The jury also found by clear and convincing evidence that the certificate of correction for claim 1 of the '882 patent was not invalid and by a preponderance of the evidence that Smith & Nephew induced infringement and contributed to the infringement of claims 13, 17, and 54 of the

'882 patent with its Saphyre, Saphyre with Suction, and Control RF products. (Id.) In addition, the jury found by a preponderance of the evidence that Smith & Nephew induced infringement and contributed to the infringement of claims 1, 3, 4, 11, 21, 23, 26, 27, 32, and 42 of the '592 patent with its Saphyre, ElectroBlade, and Control RF products.⁵ (Id.) The jury further found that Smith & Nephew did not prove by clear and convincing evidence that the patents in suit are invalid due to anticipation or that claims 13, 17, and 54 of the '882 patent are invalid for lack of enablement. (Id.) The court entered final judgment on June 20, 2003 based upon the jury's verdict. (D.I. 452)

III. STANDARD OF REVIEW

A. Motion for Judgment as a Matter of Law

To prevail on a renewed motion for judgment as a matter of law following a jury trial under Federal Rule of Civil Procedure 50(b), the moving party "'must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusions implied [by] the jury's verdict cannot in law be supported by those findings.'" Pannu v. Iolab Corp., 155 F.3d 1344, 1348 (Fed. Cir. 1998)

⁵The jury was not asked to decide whether Smith & Nephew contributed to the infringement or induced the infringement of claims 21 and 42 of the '592 patent with its Saphyre or ElectroBlade products.

(quoting Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 893 (Fed. Cir. 1984)). "'Substantial' evidence is such relevant evidence from the record taken as a whole as might be acceptable by a reasonable mind as adequate to support the finding under review." Perkin-Elmer Corp., 732 F.2d at 893. In assessing the sufficiency of the evidence, the court must give the non-moving party, "as [the] verdict winner, the benefit of all logical inferences that could be drawn from the evidence presented, resolve all conflicts in the evidence in his favor, and in general, view the record in the light most favorable to him." Williamson v. Consol. Rail Corp., 926 F.2d 1344, 1348 (3d Cir. 1991); Perkin-Elmer Corp., 732 F.2d at 893. The court may not determine the credibility of the witnesses nor "substitute its choice for that of the jury between conflicting elements of the evidence." Id. In summary, the court must determine whether the evidence reasonably supports the jury's verdict. See Dawn Equip. Co. v. Kentucky Farms Inc., 140 F.3d 1009, 1014 (Fed. Cir. 1998).

B. Motion for a New Trial

The decision to grant or deny a new trial is within the sound discretion of the trial court and, unlike the standard for determining judgment as a matter of law, the court need not view the evidence in the light most favorable to the verdict winner. See Allied Chem. Corp. v. Darflon, Inc., 449 U.S. 33, 36 (1980).

Federal Rule of Civil Procedure 59(a) provides, in pertinent part:

A new trial may be granted to all or any of the parties and on all or part of the issues in an action in which there has been a trial by jury, for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States.

New trial are commonly granted in the following situations: (1) where the jury's verdict is against the clear weight of the evidence, and a new trial must be granted to prevent a miscarriage of justice; (2) where newly-discovered evidence surfaces that would likely alter the outcome of the trial; (3) where improper conduct by an attorney or the court unfairly influenced the verdict; or (4) where the jury's verdict was facially inconsistent. See Zarow-Smith v. N.J. Transit Rail Operations, 953 F. Supp. 581, 584 (D. N.J. 1997) (citations omitted). The court, however, must proceed cautiously and not substitute its own judgment of the facts and assessment of the witnesses' credibility for the jury's independent evaluation. Nevertheless,

[w]here a trial is long and complicated and deals with a subject matter not lying within the ordinary knowledge of jurors a verdict should be scrutinized more closely by the trial judge than is necessary where the litigation deals with material which is familiar and simple, the evidence relating to ordinary commercial practices. An example of subject matter unfamiliar to a layman would be a case requiring a jury to pass upon the nature of an alleged newly discovered organic compound in an infringement action.

Lind v. Schenley Indus. Inc., 278 F.2d 79, 90-91 (3d Cir. 1960).

IV. DISCUSSION

A. Smith & Nephew's Renewed Motion for Judgment as a Matter of Law, or in the Alternative a New Trial, on Direct Infringement Grounds⁶

1. The Legal Standard for Direct Infringement

A patent is directly infringed when a person "without authority makes, uses or sells any patented invention, within the United States . . . during the term of the patent." 35 U.S.C. § 271(a) (2002). A court should employ a two-step analysis in making a direct infringement determination. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). First, the court must construe the asserted claims to ascertain their meaning and scope. See id. Construction of the claims is a question of law subject to de novo review. See Cybor Corp. v. FAS Techs., 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc). The trier of fact must then compare the properly construed claims with the accused infringing product. See id. This second step is a question of fact. See Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353 (Fed. Cir. 1998). Direct infringement occurs where each limitation of

⁶When motioning the court for a new trial under Fed. R. Civ. P. 59, Smith & Nephew appears to also move for a new trial under Fed. R. Civ. P. 50(b). Smith & Nephew premises this motion on the same grounds raised in its motion for judgment as a matter of law under Fed. R. Civ. P. 50(b). (See D.I. 456 at 33-34). The court, therefore, shall consider its Rule 50(b) motion for judgment as a matter of law as including an alternative motion for a new trial.

at least one claim of the patent is found exactly in the alleged infringer's product. See Pancuit Corp. v. Dennison Mfg. Co., 836 F.2d 1329, 1330 n. 1 (Fed. Cir. 1987). The patent owner has the burden of proving direct infringement and must meet its burden by a preponderance of the evidence. See SmithKline Diagnostics, Inc. v. Helena Lab. Corp., 859 F.2d 878, 889 (Fed. Cir. 1988) (citations omitted).

2. The '536 Patent

Smith & Nephew renews its motion for judgment as a matter of law that its accused products cannot directly infringe independent claim 45 or dependent claims 46, 47, or 56 of the '536 patent because the probes covered by the '536 patent must deliver fluid to the target site in light of the court's claim construction for the term "electrosurgical system." Smith & Nephew asserts that the probes used in its Saphyre, Control RF, and ElectroBlade products do not introduce such a fluid supply, even though they are used in the presence of electrically conducting fluid. To this end, Smith & Nephew explains that fluid is introduced to the target site by a separate piece of medical equipment like an IV bag or an Inteliject pump and that the separate equipment is not part of the "electrosurgical system." (D.I. 415 at 976, 1014) Smith & Nephew alleges that Arthrocare's expert, Dr. Nahum Goldberg, improperly ignored the requirement that an electrically conducting fluid supply be part

of the claimed system in his testimony at trial. (See D.I. 411 at 398-99) Accordingly, Smith & Nephew maintains that its products fall outside the scope of the asserted claims in the '536 patent.

The court disagrees. A jury reasonably may have discounted all testimony presented by Smith & Nephew with respect to direct infringement of the '536 patent after finding Smith & Nephew's use of the term "electrosurgical system" inconsistent with the court's claim construction. The court construed this term to mean "an assemblage or combination of things or parts forming a unitary whole." The court did not require that all elements physically interconnect as implied by Smith & Nephew. Following the court's construction, the jury likely understood that fluid may be delivered from any source (e.g., the probe itself, an IV bag, or an Intelijet pump) and still permit formation of an "electrosurgical system."

Additionally, there is ample evidence in the record upon which a jury reasonably could have concluded that the accused products meet all limitations of the asserted claims. Dr. Goldberg testified that the accused devices will only function in the presence of electrically conducting fluid. (See id. at 398-99, 405, 412) Smith & Nephew's own expert, Dr. Kenneth Taylor, also testified that the accused devices require, and will not work without, electrically conducting fluid. (See D.I. 416 at

1453-54) Dr. Taylor likewise admitted that a probe is not required to deliver fluid for the probe and fluid supply to be considered an "electrosurgical system." (See id. at 1413-16) Moreover, Dr. Taylor explained the components described in the Slager reference comprised an electrosurgical system, even though fluid was not delivered through the probe. (See id. at 1414)

Besides direct witness testimony, the jury viewed multiple video clips of the accused products in operation during "normal procedure." (See PX 105, DTX 315, DTX 316, DTX 897) In all clips, the target sites were submerged under saline fluid. (Id.) The jury further saw product literature from Smith & Nephew, namely the ElectroBlade "Instruction for Use" guide, which described the use of the ElectroBlade in conjunction with the Intelijet pump and referred to this assembly as the "Recommended System Configuration." (PX 189 at 3) On the basis of this evidence, a reasonable jury could conclude that the Saphyre, Control RF, and ElectroBlade probes form an "electrosurgical system" as required by the '536 claims and, as such, infringe the '536 patent. Accordingly, the court denies Smith & Nephew's motion for judgment as a matter of law that the '536 patent is not infringed by the accused products.

Concerning a new trial, the verdict is not against the weight of the evidence and no miscarriage of justice will result if the jury's verdict stands. Smith & Nephew did not present

evidence that so overwhelmingly favors its position that the jury clearly erred in finding that the accused products directly infringe the '536 patent. In addition, the court finds that none of the other reasons for granting a new trial, such as the discovery of new evidence or improper attorney conduct, exist under the facts at bar. Thus, the court denies Smith & Nephew's motion for a new trial as to literal infringement of the '536 patent.

B. Smith & Nephew's Renewed Motion for Judgment as a Matter of Law, or in the Alternative a New Trial, Based Upon the Validity of the Certificate of Correction for the '882 Patent

Smith & Nephew argues that its Saphyre, ElectroBlade, and Control RF probes would not directly infringe the '882 patent but for the certificate of correction that broadened the number of electrodes recited in application claim 23, which became patent claim 1, from four electrodes (i.e., an electrode terminal, an active electrode, a return electrode, and an electrically conducting terminal) to two electrodes (i.e., an electrode terminal and a return electrode). In other words, Smith & Nephew does not contest that its Saphyre, Control RF, and ElectroBlade products directly infringe the asserted claims of the '882 patent as corrected by the certificate of correction because its accused probes have only two electrodes as recited by the corrected

claims.⁷ (See D.I. 415 at 1110-1112) Rather, Smith & Nephew argues that the certificate of correction is invalid. In this regard, Smith & Nephew asserts that it was not obtained to correct a mistake, but only to broaden the claims to advance its lawsuit against Ethicon. Additionally, Smith & Nephew argues that, even if the certificate was filed to correct obvious errors, it was not manifest how such corrections should have been made.

The court disagrees. The record is replete with evidence upon which a jury reasonably could have found that the certificate of correction was validly made to correct legitimate errors in the claims. Congress enabled a patent applicant to correct errors in a patent due to the applicant's mistake in 35 U.S.C. § 255. This section provides:

Whenever a mistake of a clerical or typographical nature, or of minor character, which was not the fault of the Patent and Trademark Office, appears in a patent and a showing has been made that such mistake occurred in good faith, the Director may, upon payment of the required fee, issue a certificate of correction, if the correction does not involve such changes in the patent as would constitute new matter or would require re-examination. Such patent, together with the certificate, shall have the same effect and operation in law on the trial of actions for causes thereafter arising as if the same had been originally issued in such corrected form.

⁷Smith & Nephew contends that its accused products, however, do not infringe the original claims of the '882 patent. (See also D.I. at 1110)

35 U.S.C. § 255 (2000). This section enumerates two specific kinds of applicant error which may be corrected through a certificate of correction: (1) errors of a clerical or typographical nature; and (2) errors of a minor character. The Federal Circuit has noted that the words of § 255 do not preclude broadening corrections. Superior Fireplace Co. v. The Majestic Prods. Co., 270 F.3d 1358, 1371 (Fed. Cir. 2001). However, the Federal Circuit opined that " a broadening correction of a clerical or typographical error [may] be allowed only where it is clearly evident from the specification, drawings, and prosecution history how the error should appropriately be corrected." Id. at 1373. With regard to mistakes of a minor character, the Federal Circuit has interpreted the language of § 255 to exclude mistakes that broaden a claim. Id. at 1374. The Federal Circuit further has held that the clear and convincing standard is applicable to challenges to the validity of a certificate of correction. Id. at 1367.

Applying these principles to the facts at bar, the court notes that Mr. John Raffle, Arthrocare's in-house counsel, filed an amendment on March 25, 1997 prior to the '882 patent grant to change the phrase "active electrode" to "electrode terminal." Mr. Raffle testified that he attempted to make this change for every occurrence of the phrase "active electrode" in the claims. (See D.I. 417 at 1524-26) Mr. Raffle also testified that the

phrase "the active electrode" in uncorrected application claim 23 lacked antecedent basis because the precise words "an active electrode" did not appear earlier in the claim set. (See id. at 1515-16) Based upon this testimony, the jury could have inferred that Mr. Raffle inadvertently overlooked two occurrences of the phrase "active electrode" in his amendment and that reference to "the active electrode" after the phrase "an electrode terminal" was a typographical error. A jury likewise reasonably could have concluded that both the typographical error and the proper way to correct it were evident in light of the prosecution history of the '882 patent. Accordingly, the court denies Smith & Nephew's motion for judgment as a matter of law that the certificate of correction is invalid.

With respect to a new trial, the weight of the evidence does not warrant a new trial to avoid a miscarriage of justice. Arthrocure offered sufficient evidence upon which a jury could have found that the certificate of correction is valid. Hence, the court denies Smith & Nephew's motion for a new trial premised on the invalidity of the certificate of correction for the '882 patent.

C. Smith & Nephew's Renewed Motion for Judgment as a Matter of Law, or in the Alternative a New Trial, on Contributory and Inducing Infringement Grounds

1. The Legal Standard for Contributory Infringement

The doctrine of contributory infringement is codified at 35 U.S.C. § 271(c):

Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

The Federal Circuit has explained that this form of infringement is premised on the idea that a defendant who displays sufficient culpability should be held liable as an infringer, even though he did not technically make, use, or sell a patented invention.

Hewlett-Packard Co. v. Bausch & Lomb, Inc., 909 F.2d 1464, 1469 (Fed. Cir. 1990). The Federal Circuit also has noted that “[s]uch liability was under a theory of joint tortfeasance, wherein one who intentionally caused, or aided and abetted, the commission of a tort by another was jointly and severally liable with the primary tortfeasor.” Id. Based upon the language of § 271(c), there can be no contributory infringement in the absence of direct infringement. See Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336, 341-42 (1961). In addition,

there can be no contributory infringement without knowledge that the component made or sold was especially adapted for a particular use proscribed by a known patent. See Hewlett-Packard Co., 909 F.2d at 1469. Actual intent to cause or contribute to infringement is not necessary to establish contributory infringement. Id. Instead, “[a] seller of a ‘material part’ of a patented item may be a contributory infringer if he makes a non-staple article that he knows was ‘especially made or especially adapted for use in an infringement of such patent.’” Husky Injection Molding Sys. v. R&D Tool & Eng’g Co., 291 F.3d 780, 784 (Fed. Cir. 2002) (citing 35 U.S.C. § 271(c); Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 219 (1980)). Furthermore, the “occasional and aberrant use of these products, [even] where they are clearly designed to be used in a system specified in the claims of a patent, does not rise to the level of ‘a staple article or commodity of commerce suitable for substantial non-infringing use.’” Preemption Devices v. Minnesota Mining & Mfg. Co., 630 F. Supp. 463, 471 (E.D. Pa. 1985) (citing Dennison Mfg. Co. v. Ben Clements & Sons, Inc., 467 F. Supp. 391, 428 (S.D.N.Y. 1979)).

2. The Legal Standard for Inducing Infringement

Pursuant to 35 U.S.C. § 271(b), “[w]hoever actively induces infringement of a patent shall be liable as an infringer.” As with contributory infringement, direct infringement is a

prerequisite to inducing infringement. Met-Coil Sys. Corp. v. Korners Unlimited, Inc., 803 F.2d 684, 687 (Fed. Cir. 1986). Additionally, the alleged infringer must have knowingly induced infringement. Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 553 (Fed. Cir. 1990) (citing Water Techs. Corp. v. Calco, Ltd., 850 F.2d 660, 668 (Fed. Cir. 1988)). The Federal Circuit has stated that "although section 271(b) does not use the word 'knowing, the case law and legislative history uniformly assert such a requirement." Water Techs., 850 F.2d at 668. In this regard, mere knowledge of the acts alleged to constitute inducement is not enough. Manville Sales Corp., 917 F.2d at 553. Rather, the plaintiff has the burden of showing that "the alleged infringer's actions induced infringing acts and that he knew or should have known his actions would induce actual infringements." Id.

3. The Direct Infringement Prerequisite for Contributory and Inducing Infringement⁸

Considering the direct infringement prerequisite for the acts of contributory and inducing infringement, Smith & Nephew

⁸Smith & Nephew argues that it is not liable for contributory or inducing infringement because its accused products do not directly infringe the '536 patent. The court shall not consider this argument in the instant analysis because a jury found that Smith & Nephew directly infringed the '536 patent and the court herein denied Smith & Nephew's motion for judgment as a matter of law on direct infringement grounds for this patent. See supra, Section IV, 1, A.

Recall also Smith & Nephew did not argue noninfringement of the '882 patent as corrected by the certificate of correction.

argues that the Saphyre, Control RF, and ElectroBlade probes do not practice the limitations of asserted claims of the '592 patent. Specifically, Smith & Nephew contends that the return electrodes on its products frequently contact target tissue during the performance of the method for applying electrical energy recited in claims 1 and 23 of the '592 patent.⁹ Claim 1 requires "positioning a return electrode . . . such that [it] is not in contact with the body structure," and claim 23 requires "spacing a return electrode away from the body structure." ('592 patent, col. 24 at ll. 13-14; col. 25 at ll. 48) Smith & Nephew alleges that Dr. Goldberg improperly applied a temporal limitation in testifying that the "only way not to infringe this claim with the device is to make sure that the return electrode . . . is always in contact **when the energy is on.**" (D.I. 411 at 421-22) (emphasis added) Smith & Nephew particularly notes that the return electrodes on its products contact tissue while the probe is being positioned before energy is applied (i.e., during the second step enumerated in claims 1 and 23). Smith & Nephew, therefore, advocates that a reasonable jury could not find that

⁹Procedurally, Smith & Nephew raised the issue of direct infringement of the '592 patent in a motion for judgment as a matter of law. As the court previously noted above, this issue was not presented to the jury. See supra, Introduction, n. 1. The court, therefore, construes Smith & Nephew's argument in the context of its motion for judgment as a matter of law on both contributory and inducing infringement grounds.

the use of any of its accused products satisfies the return electrode "not in contact/spaced away" limitations given this contact time. (See D.I. 354 at 7)

Viewing the record in a light most favorable to Arthocare as the non-moving party, the court disagrees with Smith & Nephew's argument. The record reflects that there are times when the return electrode is not in contact with target tissue and all of the other claim limitations are performed, thereby supporting the jury verdict of literal infringement. To this end, Smith & Nephew's expert, Dr. Michael Choti, admitted that when the active electrode on the Control RF probe is positioned near the target site and energy is applied, the return electrode does not always contact tissue. (See D.I. 412 at 743-744) Ms. Karen Drucker, the ElectroBlade project manager, and Ms. Kate Knudsens, the Saphyre project manager, similarly acknowledged that video clips of the accused products in operation show times when the return electrodes of the ElectroBlade and Saphyre probes, respectively, were not in contact with tissue while energy was applied. (See D.I. 415 at 1036, 985) Mr. Warren Heim, Smith & Nephew's consultant, also testified that the Control RF probe was designed so that the return electrode would not contact tissue during use. (See D.I. 414 at 957-58) Additionally, Mr. Joe McCreary, the Saphyre marketing manager, testified that the Saphyre can function even if the return electrode is not in contact with

tissue. (See D.I. 412 at 555) Moreover, the Saphyre Sales Guide warns that "care should be taken to prevent tissue contact with the return electrode on the Saphyre probe shaft." (PX 390 at 37) The ElectroBlade Sales Training CD likewise instructs users to "ensure that the entire tip including the return electrode is immersed in saline, to "present" the active electrode to the tissue, and "to use suction to pull bleeding tissue to the blade for coagulation." (PX 199 at 11, 7) The Control RF "Instructions for Use" further informs doctors to be sure that the active and return electrodes are "completely surrounded" by electrically conducting fluid during use." (PTX 205 at 1) Considering the totality of this evidence, a jury reasonably could have found that Smith & Nephew's accused products meet the "not in contact/spaced away" limitations of the asserted claims and thereby directly infringe the '592 patent.

4. Contributory Infringement

Smith & Nephew asserts that its products have "substantial non-infringing uses" such that they were not designed to infringe the asserted claims of the patents in suit. Specifically, Smith & Nephew claims that these non-infringing uses include: (1) operation of the probes to apply energy while the return electrode touches tissue (i.e., noninfringement of the '592 patent); (2) operation of the probes to apply energy without creating a vapor layer, thereby achieving coagulation instead of

ablation (i.e., noninfringement of the '882 patent); and (3) operation of the probes as part of an "electrosurgical system" that does not have a fluid supply (i.e., noninfringement of the '536 patent).

The court is again unpersuaded by these arguments. The evidence of record for the '592 patent discussed above shows that the Saphyre, ElectroBlade, and Control RF probes were constructed to prevent the return electrode from contacting tissue. The court finds that similar evidence exists with respect to the '882 and '536 patents. In particular, Smith & Nephew refers to its Saphyre product line as "ablation" probes in its sales guides. (See PX 381 at 1, PX 390 at 10). Smith & Nephew also markets its Saphyre and Control RF probes for use in ablation, not coagulation, even though both may provide coagulation. (See PX 390 at 4, PX 593 at 11, 29, PX 205 at 1) Additionally, several witnesses at trial testified that the Saphyre, ElectroBlade, and Control RF probes must be used with electrically conducting fluid. (See D.I. 411 at 397-98, 405, 412; D.I. 414 at 848; D.I. 415 at 1013) More specifically, Mr. Sparks and Ms. Drucker testified that electrically conducting fluid must be delivered to the target site in arthroscopic surgery. (See D.I. at 814-16; D.I. 415 at 1013-14) A reasonable juror, taking all of this evidence into account, could have concluded that the accused probes were designed to infringe and that the occasional or

aberrant use of one of them in a non-infringing manner, as suggested by Smith & Nephew, does not constitute a substantial noninfringing use. Therefore, the court denies Smith & Nephew's motion for judgment as a matter of law that it is not liable for contributing to the infringement of the patents in suit.

As to a new trial, none of the reasons for granting a new trial exists in the instant case. That is, the jury's verdict is not against the weight of the evidence. Rather, both sides presented evidence to support their respective positions. Additionally, no miscarriage of justice will result by upholding the jury's verdict. For these reasons, the court denies Smith & Nephew's motion for a new trial on contributory infringement grounds.

5. Inducing Infringement

Smith & Nephew argues that it is not liable as an inducing infringer because Arthrocare failed to prove that Smith & Nephew intends to cause its customers to infringe the asserted claims of the patents in suit. The court finds that Smith & Nephew's arguments are not well founded and that sufficient evidence exists in the record to support the jury's verdict of inducing infringement. In particular, Ms. Knudsen and Mr. Heim testified that they read the patents in suit before the Saphyre probe design was complete and prior to design efforts commenced for the ElectroBlade and Control RF probes. (D.I. 415 at 991; D.I. 414

at 936-37, PX 735 at 23-25) They further stated that they evaluated Arthrocare's patented products prior to designing the accused products. (D.I. 414 at 951, D.I. 415 at 977-78) On this basis, a jury reasonably could have found that Smith & Nephew knew or should have known that its customers would directly infringe the patents in suit when using the Saphyre, ElectroBlade, and Control RF probes. Consequently, the court denies Smith & Nephew's motion for judgment as a matter of law that it is not liable for inducing infringement.

Regarding a new trial, the jury's verdict of inducing infringement is not against the clear weight of the evidence. Moreover, no miscarriage of justice will result if this verdict stands. Accordingly, the court concludes that a new trial is not warranted and denies Smith & Nephew's motion for a new trial on inducing infringement grounds.

D. Smith & Nephew's Renewed Motion for Judgment as a Matter of Law, or in the Alternative a New Trial, on Invalidity Grounds

Smith & Nephew renewed its motion for judgment as a matter of law that the patents in suit are invalid based on prior art grounds. Before reaching the substance of this motion, Arthrocare challenges Smith & Nephew's right to raise this motion claiming that Smith & Nephew failed to preserve the issue of invalidity before the case was submitted to the jury pursuant to Fed. R. Civ. P. 50(a). Rule 50(b) permits consideration of such renewed

motions for judgment as a matter of law only when a motion for a directed verdict has been made at the close of the evidence offered by an opponent. In pertinent part, Rule 50(b) states:

If, for any reason, the court does not grant a motion for judgment as a matter of law made at the close of all the evidence, the court is considered to have submitted the action to the jury subject to the court's later deciding the legal questions raised by the motion. The movant may renew its request for judgment as a matter of law by filing a motion no later than 10 days after entry of judgment.

Rule 50(a) requires that "[a] motion for a directed verdict shall state the specific grounds therefor." This requirement is in place to afford the non-moving party with the opportunity to reopen its case and present additional evidence. See Bonjorno v. Kaiser Aluminum & Chem. Corp., 752 F.2d 802, 814 (3d Cir. 1984) (citing Lowenstein v. Pepsi-Cola Bottling Co., 536 F.2d 9, 11 (3d Cir. 1976)).

In the case at bar, Smith & Nephew motioned for a directed verdict three times. It first made a Rule 50(a) motion at the close of Arthrocare's case. (See D.I. 415 at 1161) It made a second Rule 50(a) motion at the close of all the evidence. (See D.I. 417 at 1549) Smith & Nephew then renewed this motion prior to the jury charge. (See D.I. 418 at 1700) Since the issue of invalidity had not been presented when Smith & Nephew initially moved for a directed verdict, the court finds that Smith & Nephew's first motion was not directed to the invalidity of the patents in suit. The court notes, however, that the issue of

invalidity was in evidence at the time Smith & Nephew made its second and third motions. The court also notes that it indicated after these latter motions that Smith & Nephew's rights were reserved, despite the fact that Smith & Nephew did not specifically state the precise grounds for its motions. (See D.I. 417 at 1549; D.I. 418 at 1700). As well, the court did not require any argument concerning the motions when raised and precluded Smith & Nephew from discussing them. The court, therefore, concludes that it would be unjust to Smith & Nephew not to consider its renewed motion for judgment as a matter of law. Accordingly, the court will consider the instant motion.

1. The Legal Standard for Invalidity

A patent is presumed valid, and each claim whether in independent, dependent, or multiple dependent form is presumed to be valid independent of the validity of other claims. 35 U.S.C. § 282 (2003). The party asserting invalidity, consequently, has the burden of proof. Id. This burden is satisfied only by proving facts establishing invalidity by clear and convincing evidence. Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1377 (Fed. Cir. 2003) (citing Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc., 98 F.3d 1563, 1569 (Fed. Cir. 1996)). The patentee, therefore, need not submit any evidence to support the validity of a patent. Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1570 (Fed.

Cir. 1986). Moreover, the challenger's burden is especially difficult to meet when the art relied on at trial was considered by the PTO. BOC Healthcare, Inc. v. Nellcor, Inc., 892 F. Supp. 598, 602 (D. Del. 1995). Indeed, the Federal Circuit has stated:

When no prior art other than that which was considered by the PTO examiner is relied on by the attacker, he has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners who are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents.

American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359 (Fed. Cir. 1984).

a. Invalidity on Anticipation Grounds

A patent is invalid for anticipation under 35 U.S.C. § 102 if a single prior art reference explicitly discloses each and every limitation of the claimed invention. Lamar Marine, Inc. v. Baronet, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987). The Federal Circuit has stated that "[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention."

Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1576 (Fed. Cir. 1991). In determining whether a patented invention is explicitly anticipated, the claims are read in the context of the patent specification in which they arise and in which the invention is described. Glaverbel Societe Anonyme v.

Northlake Mktg. & Supply, Inc., 45 F.3d 1550, 1554 (Fed. Cir. 1995). The prosecution history and the prior art may be consulted if needed to impart clarity or to avoid ambiguity in ascertaining whether the invention is novel or was previously known in the art. Id.

A prior art reference also may anticipate without explicitly disclosing a feature of the claimed invention if that missing characteristic is inherently present in the single anticipating reference. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991). The Federal Circuit has explained that an inherent limitation is one that is necessarily present and not one that may be established by probabilities or possibilities. Id. That is, “[t]he mere fact that a certain thing may result from a given set of circumstances is not sufficient.” Id. The Federal Circuit also has observed that “[i]nherency operates to anticipate entire inventions as well as single limitations within an invention.” Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1380 (Fed. Cir. 2003). Moreover, recognition of an inherent limitation by a person of ordinary skill in the art before the critical date is not required to establish inherent anticipation. Id. at 1377.

An anticipation inquiry involves two steps. First, the court must construe the claims of the patent in suit as a matter of law. See Key Pharm. v. Hercon Labs Corp., 161 F.3d 709, 714

(Fed. Cir. 1998). Second, the finder of fact must compare the construed claims against the prior art. Id. A finding of anticipation will invalidate the patent. Applied Med. Res. Corp. v. U.S. Surgical Corp., 147 F.3d 1374, 1378 (Fed. Cir. 1998)

i. The '536 Patent

Smith & Nephew charges that the '536 patent is anticipated by several prior art references. In particular, Smith & Nephew contends that the '499 patent, the '007 patent, the '198 patent, and the Elsasser/Roos article each disclose all of the limitations of the invention claimed in the '536 patent. As support for its anticipation argument, Smith & Nephew asserts that its expert Dr. Taylor testified that the '198, '499, and '007 patents and the Elsasser/Roos article individually disclose every limitation recited in claims 45, 46, and 56 of the '596 patent. (See D.I. 416 at 1294-1313) Smith & Nephew also contends that Arthocare did not offer any evidence to contradict or rebut this testimony, but instead cross-examined Dr. Taylor about select claim limitations to confuse and mislead the jury.

Viewing the record in a light most favorable to Arthocare as the verdict winner, the court is unpersuaded by Smith & Nephew's argument. The evidence presented at trial reasonably supports the jury's verdict of infringement. The PTO specifically considered the prior art effect of the '499 and '007 patents during the prosecution of the '536 patent and allowed the

asserted claims. The PTO also considered the '198 patent and the Elsasser/Roos article during the reexamination of the '536 patent and issued a notice of intent to issue reexamination certificate. (See D.I. 417 at 1537-1540) The court concludes that this evidence was sufficient to convince a jury of the validity of the '536 patent.

Additionally, Arthocare solicited testimony from Dr. Taylor establishing that each of the asserted references fails to disclose at least one limitation of the asserted claims. Dr. Taylor admitted on cross-examination that the '499 patent does not disclose a current flow path through electrically conducting fluid as required by the asserted '536 claims. Dr. Taylor testified that it instead discloses inserting the electrodes directly into the target tissue, thereby facilitating electrical current flow between the axial and outer electrodes through the tissue. (See D.I. 416 at 1409-12) Dr. Taylor also stated in his deposition that both electrodes disclosed in the '007 patent have substantially the same current density (i.e., meaning that the '007 patent did not disclose a return electrode), though asserted at trial that his deposition testimony was in error. (See id. at 1383-85) Dr. Taylor likewise testified that the '007 patent and the '198 patent do not disclose the location of a connector with respect to the proximal end of the shaft as required by the asserted claims. (See id. at 1400; 1371) Additionally, Dr.

Taylor testified that the Elsasser/Roos article fails to explicitly describe the function for the structure located at the proximal end of the disclosed probe. (See id. at 1298) Dr. Taylor further testified on cross-examination that neither the '198 patent nor the Elsasser/Roos article disclose the use of either saline or Ringer's lactate, both of which are electrically conducting fluids. (See id. at 1340-43) Dr. Taylor, in fact, stated that the references do not distinguish between the electrically non-conducting liquid used with monopolar devices and the liquid used in bipolar devices. (Id.) Moreover, Dr. Taylor stated that there would be no need for the steel band described in Figure 5 of the '198 patent if the liquid shown in Figure 5 was electrically conducting. (See id. at 1345) Given the totality of this evidence, a jury may have properly found that the prior art references do not anticipate the '536 invention. Therefore, the court denies Smith & Nephew's motion for judgment as a matter of law that the asserted claims of the '536 patent are invalid on anticipation grounds.

With respect to a new trial, no miscarriage of justice will result if the jury's verdict of validity as to the '592 patent stands. Mindful not to substitute its own judgment of the facts and the credibility of the witnesses for those of the jury, the verdict is neither against the weight of the evidence nor facially inconsistent. Furthermore, since the conclusion of

trial, no new evidence has surfaced to alter the outcome of the trial. The court, consequently, denies Smith & Nephew's motion for a new trial on anticipation grounds for the '592 patent.

ii. The '882 Patent

Smith & Nephew contends that the '138 patent and the Slager article individually disclose each and every limitation recited in the asserted claims of the '882 patent. Smith & Nephew specifically argues that the '138 patent anticipates claims 1, 13, and 54 and that the Slager article anticipates claims 1, 13, 17, and 54. Smith & Nephew relies on the expert testimony of Dr. Taylor and Dr. Kim Manwaring for support. (See id. at 1313-1320; D.I. 414 at 886-96) As with the '536 patent discussed above, Smith & Nephew maintains that Arthocare failed to present rebuttal evidence to contradict the experts, but instead misleadingly cross-examined these experts regarding particular claim limitations to confuse the jury.

The court, nonetheless, finds that a reasonable jury could have concluded on the record before it that several differences exist between the '882 invention and the '138 patent and the Slager article such that Smith & Nephew failed to prove anticipation by clear and convincing evidence. Focusing first on the '138 patent, Dr. Manwaring admitted that this reference discloses a spark discharge followed by vaporization of the fluid. (See id. at 907-908) In contrast, claims 1, 13, 17, and

54 of the '882 patent disclose vaporization of the electrically conducting fluid followed by electrical discharge. Claim 13 also requires generation of photons having a wavelength in the ultraviolet spectrum. Dr. Manwaring stated at trial that the '138 patent does not explicitly mention ultraviolet photons and that he was unaware of any testing that established that the '138 device emits ultraviolet photons. (See id. at 897-98) Similarly, Dr. Taylor confirmed that he performed no testing to establish that a device built according to the '138 patent generates ultraviolet light. (See D.I. 416 at 1420-21) Finally, claim 54 of the '882 patent discloses evacuating the fluid beyond the vicinity of the target tissue. Both Dr. Manwaring and Dr. Taylor admitted that the '138 patent, in contrast, discloses drawing the fluid into the catheter tip where it remains in the vicinity of the target tissue. (See D.I. 414 at 904-05; D.I. 416 at 1432-33)

Turning to consider the Slager article, Dr. Taylor agreed that it does not disclose the application of energy to a "target site on a patient body structure" as required by the preamble of claims 1 and 28. Dr. Taylor instead testified that the Slager article discussed the application of energy to a tissue in a lab dish. (See id. at 1426-27) Since sufficient evidence exists for the jury to have concluded that the '138 patent and the Slager article do not disclose each and every limitation found in the

claims of the '882 patent, Smith & Nephew is not entitled to prevail on its motion for judgment as a matter of law. The court, consequently, denies Smith & Nephew's motion for judgment as a matter of law that the '882 patent is invalid on anticipation grounds.

Addressing Smith & Nephew's motion for a new trial on anticipation grounds, Smith & Nephew has failed to demonstrate that the verdict is against the weight of the evidence or that a new trial is necessary to remedy a miscarriage of justice. For these reasons, the court denies Smith & Nephew's motion for a new trial on anticipation grounds as to the '882 patent.

iii. The '592 Patent

Smith & Nephew asserts that the '007 patent and the Slager article each recite all the limitations of the asserted claims of the '592 patent. Smith & Nephew relies on Dr. Taylor's testimony to support this anticipation argument and, as with the '536 and 882 patents, again claims that Arthocare failed to elicit any rebuttal testimony. Rather, Smith & Nephew charges that Arthocare misleadingly cross-examined Dr. Taylor regarding certain claim limitations to cause confusion among the jurors.

Substantial evidence exists in the record to distinguish the '592 invention from the cited prior art references in support of the jury's verdict of validity. The '592 patent contains the same "return electrode" limitation as the '536 patent. As

discussed above in relation to the '536 patent, the '007 patent does not disclose a return electrode limitation. Additionally, the '007 patent fails to disclose the waveform necessary to determine whether it anticipates the 500 to 1,400 volts peak to peak recited in claim 21.¹⁰ Dr. Taylor admitted that when he opined that the '007 patent discloses a voltage in the range of 500 to 1,400 volts peak-to-peak, he presumed that the wave form was a sine wave since this is the most common form used. (See id. at 1401-1404) In light of this presumption, a jury reasonably may have dismissed Dr. Taylor's testimony concerning the anticipatory effect of the '007 patent on the '592 patent. As to the Slager article, claims 1 and 28 of '592 patent contain the same "on or within a patient's body" preamble language as claims 1 and 26 of '882 patent. The Slager article, on the other hand, only discloses the application of energy to tissue in a lab dish as noted above. Furthermore, claims 1 and 23 of the '592 patent specify that the return does not touch the body structure. Dr. Taylor testified that he was unable to determine the location

¹⁰The '007 patent discloses a 20 to 200 root-mean-square voltage. Presume that the wave form produced by the generator is a sine wave, the court acknowledges that this root-mean-square voltage range may be converted to a peak-to-peak voltage using a 2.83 conversion factor. Applying this factor to the voltage range disclosed in the '007 patent, the resulting peak-to-peak voltage for the 200 volts root mean square is 583 volts peak-to-peak. However, using the conversion factor of 2 for a square wave, the 200 volts root-mean-square converts to 400 volts peak-to-peak.

of the return electrode in the Slager article. (See *id.* at 1414-18) Given this evidence of the differences between these prior art references and the claimed invention, the jury verdict was not erroneous. Accordingly, the court denies Smith & Nephew's motion for judgment as a matter of law that the '592 patent is invalid on anticipation grounds.

The court also denies Smith & Nephew's motion for a new trial as to the '592 patent. None of the common reasons for granting a new trial exist under the facts at bar. That is, the jury's verdict is not against the weight of the evidence or facially inconsistent. Likewise, no miscarriage of justice will result if the verdict stands.

b. Invalidity on Enablement Grounds

The statutory basis for the enablement requirement is found in 35 U.S.C. § 112, paragraph 1, which provides in relevant part:

The specification shall contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In order to be enabling, a specification must teach those skilled in the art how to make and to use the full scope of the claimed invention without undue experimentation. Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1365 (Fed. Cir. 1997). The Federal Circuit has explained that "patent protection is granted in

return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable ... Tossing out the mere germ of an idea does not constitute enabling disclosure." Id. at 1366.

In determining whether undue experimentation is required to practice a claimed invention, a court may consider several factors, including: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance disclosed in the patent; (3) the presence or absence of working examples in the patent; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (6) the predictability of the art; and (7) the breadth of the claims. In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). Consideration of each of these factors, however, is not a mandatory part of a court's analysis. Rather, a court is only required to consider those factors which are relevant to the facts of each case. See Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200, 1213 (Fed. Cir. 1991). Thus, the enablement requirement is a question of law based on underlying factual inquiries. In re Wands, 858 F.2d at 737.

Smith & Nephew argues that the asserted claims in the '882 patent are not properly enabled because the "cold ablation"

process is not adequately described in the specification.¹¹ The '882 specification states that the cold ablation process is dependent upon a variety of factors including "the number of electrode terminals, electrode size and spacing, electrode surface area, asperities and sharp edges on the electrode surfaces, electrode materials, applied voltage and power, current limiting means, such as inductors, electrical conductivity of the fluid in contact with the electrodes, density of the fluid, and other factors." ('882 patent, col. 11 at ll. 8-13) Smith & Nephew contends that while the requisite variables are enumerated in the specification, it fails, nevertheless, to specify what particular combination should be used to achieve optimal cold ablation. Smith & Nephew supports this argument with Dr. Taylor's testimony regarding preferred voltage ranges, materials, frequencies, fields, power levels, contract surface area values and distances for the active electrode. (See D.I. 416 at 1436-38)

The jury, however, reasonably may have disregarded Dr. Taylor's testimony, finding it to be both conclusory and entirely solicited by counsel's line of direct questioning. Dr. Taylor testified that he "blanked" on invalidity grounds other than

¹¹The cold ablation process involves "applying a high frequency voltage between the active electrode and the return electrode to develop high electric field intensities in the vicinity of the target tissue site." ('882 patent, col. 10 at ll. 41-44) The high electric field causes the tissue to completely disintegrate. (Id. at ll. 44-54)

anticipation; consequently, he was led into a discussion of enablement by trial counsel. In relevant part, Dr. Taylor testified as follows:

Q: Do you have any other basis for believing that the claims of the '882 patent are invalid?

A: **I am sorry, I am blanking on this.**

* * *

Q: Does the '882 patent teach anything about how to achieve a new phenomenon that is different than the principle of operation of conventional electrosurgical devices?

A: No, it doesn't. I was perplexed and, frankly, am still perplexed about the overall phenomenon of [c]oblation.

Q: And is that defense also sometimes called nonenablement?

A: Yes, it is.

Q: Do you have an opinion as to whether the claims of the '882 patent are enabled to the extent it claims a new phenomenon?

A: Yes, I have an opinion.

Q: What is that opinion?

A: That it is not.

Q: Thank you.

(Id. at 1323-1325) (emphasis added) Based on the above record, the jury had sufficient grounds to conclude that Smith & Nephew had failed to prove by clear and convincing evidence that the '882 patent was not enabled and invalid. In turn, the court denies Smith & Nephew's motion for judgment as a matter of law that the '882 patent is invalid on enablement grounds.

Regarding a new trial, the verdict was not against the clear weight of evidence. Likewise, the jury's verdict will not lead to a miscarriage of justice. Thus, the court denies Smith &

Nephew's motion for a new trial on enablement grounds as to the '882 patent.

E. Smith & Nephew's Motion for A New Trial on the Basis of Improperly Admitted/Excluded Evidence

Smith & Nephew contends that the court erred in admitting and excluding select evidence such that a new trial is warranted. Specifically, Smith & Nephew argues that the following evidence was improperly excluded: (1) Arthrocare's sworn 510(k) submissions to the Food and Drug Administration ("FDA"); (2) testimony regarding those submissions from Dr. Hira A. Thapliyal, a co-inventor named on the patents in suit; (3) testimony regarding the certificate of correction from Mr. Warren Heim, a consultant to Smith & Nephew from Team Medical; (4) Judge Orrick's opinion that the '198 patent anticipated one of the patents in suit; and (5) testimony from Dr. Manwaring regarding ultraviolet photon emission test results. Smith & Nephew also contends that evidence of copying and Smith & Nephew marketing documents were improperly admitted. Federal Rule of Civil Procedure 61 requires a court to disregard harmless evidentiary errors. In pertinent part, Rule 61 states:

No error in either the admission or the exclusion of evidence . . . is ground for granting a new trial . . . unless refusal to take such action appears to the court inconsistent with substantial justice. The court at every stage of the proceeding must disregard any error or defect in the proceeding which does not affect the substantial rights of the parties.

A court's inquiry in evaluating a motion for a new trial on the basis of trial error is, therefore, twofold: "(1) whether an error was in fact committed, and (2) whether that error was so prejudicial that denial of a new trial would be 'inconsistent with substantial justice.'" Finch v. Hercules Inc., 941 F. Supp. 1395, 1414 (D. Del. 1996) (internal citation omitted). With respect to the second prong of this two-part test, a new trial must be granted unless "it is highly probable that [the erroneous ruling] did not affect the [objecting party's] substantial rights." Bhaya v. Westinghouse Electric Corp., 709 F. Supp. 600, 601 (E.D. Pa. 1989) (quoting McQueeney v. Wilmington Trust Co., 779 F.2d 916, 928 (3d Cir. 1985)).

The court has reviewed its rulings concerning the evidence in issue consistent with the first prong and finds no error was in fact committed. As such, the court need not consider whether denial of a new trial would be inconsistent with substantial justice as set forth in the second prong. The court considers each item of evidence in dispute in further detail below.

1. Exclusion of Arthrocare's FDA 510(k) Submissions and Dr. Thapliyal's Testimony

Smith & Nephew argues that Arthrocare's 510(k) submissions to the FDA and Dr. Thapliyal's testimony regarding those submissions qualify as admissions against interest by a party opponent and should have been admitted into evidence as relevant

to the issues of anticipation and enablement.¹² In particular, Smith & Nephew charges that the submissions demonstrate that the commercial embodiments of the patents in suit have the same principles of operation as prior art devices. The court rejects Smith & Nephew's argument and maintains that these submissions are irrelevant to invalidity, just as the court originally concluded when it ruled on Smith & Nephew's motion in limine.

(See D.I. 367 at ¶15; D.I. 410 at 193) Anticipation is determined by comparing the limitations of the asserted claims, not of commercial embodiments as described in 510(k) submissions, to the disclosure found in a single piece of prior art.

Enablement is evaluated based on the teachings found in the specification, not on those present in 510(k) submissions.

Therefore, since the 510(k) submissions are not relevant to the substantive issues at bar, the exclusion of these documents and corresponding testimony was not in error. Accordingly, the court denies Smith & Nephew's motion for a new trial on the basis of the exclusion of Arthrocare's 510(k) submissions and Dr. Thapliyal's testimony about these submissions.

¹²A 510(k) submission to the FDA is a "submittal[] of engineering and clinical information which [is] provided to the FDA to permit that agency to assess the safety and effectiveness of a new product with regard to a predicate product which is already on the market." Sunrise Med. HHG, Inc. v. AirStep Corp., 95 F. Supp. 2d 348, 405 (W.D. Pa. 2000).

2. Exclusion of Mr. Heim's Testimony

Smith & Nephew argues that it sought to introduce testimony at trial from Mr. Heim to support its argument that the certificate of correction was invalid. Specifically, Smith & Nephew contends that Mr. Heim was prepared to testify that he did not recognize the possibility of an error in the "active electrode" claim language found in the '882 patent as originally issued prior to the certificate of correction. On review, the court finds that its decision to limit Mr. Heim's testimony to the subject matter of his deposition was correct.

Federal Rule of Civil Procedure 37(c)(1) provides in pertinent part:

A party that without substantial justification fails to disclose information required by Rule 26(a) or 26(e)(1), or to amend a prior response to discovery as required by Rule 26(e)(2), is not, unless such failure is harmless, permitted to use as evidence at a trial, at a hearing, or on a motion any witness or information not so disclosed.

The court excluded this testimony because Mr. Heim did not discuss the substance of his trial testimony in his deposition. That is, approximately one week prior to the start of trial, Arthocare deposed Mr. Heim and asked him what he expected to testify about at trial. Smith & Nephew counsel instructed Mr. Heim not to respond to the question citing attorney-client privilege and the work product doctrine. Finding such instruction to be improper gamesmanship under Rule 37(c), the

court limited Mr. Heim's testimony to the substance of his deposition testimony. (See D.I. 413 at 944) Additionally, the court is troubled by Smith & Nephew's use of Mr. Heim's testimony. Despite identifying him as a fact witness, Smith & Nephew appears to employ him as an expert concerning the validity of the certificate of correction. (See id. at 939) In light of both these concerns, the court denies Smith & Nephew's motion for a new trial on grounds that Mr. Heim's testimony was improperly limited.

3. Exclusion of Judge Orrick's Opinion

Smith & Nephew argues that the findings of fact relating to the '536 and '882 patents made by Judge Orrick following a preliminary injunction hearing during the course of the Arthocare v. Ethicon, Inc. litigation are relevant to both the presumption of validity and the validity of the '536 and '882 patents. In particular, Smith & Nephew charges that Judge Orrick's determination that the '198 patent describes "a bipolar electrosurgery device intended to be used in electrically conductive fluid, with electrical current flowing between the active and return electrodes through the fluid" should have been admitted since the parties at bar dispute whether the '198 patent discloses electrically conducting fluid. (D.I. 321, ex. A at 17) The court disagrees. Judge Orrick rendered his findings of fact in the context of a preliminary injunction motion and concluded

that there were substantial questions about the validity of claim 45 of the '536 patent, claims 1, 26, 28, and 32 of the '882 patent, claims 40 and 44 of the '909, and claim 101 of the '281 patent. His interlocutory decision does not alter the presumption of validity; a patent is presumed valid and remains so unless and until final judgment is entered otherwise. See 35 U.S.C. §282 (2003). Additionally, findings of fact made in litigation unrelated to the present suit do not have a presumptive effect. In the instant litigation, the jury was charged with determining the validity of the asserted patents after considering the evidence presented at trial in accordance with the court's instructions. Any reference to Judge Orrick's opinion potentially would have confused the jury regarding their role in deciding such validity. Moreover, the burdens of proof associated with a preliminary injunction hearing differ from those employed at trial. In this regard, the Federal Circuit has observed that "[v]alidity challenges during preliminary injunction proceedings can be successful, that is, they may raise substantial questions of invalidity, on evidence that would not suffice to support a judgment of invalidity at trial."

Amazon.com v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1358 (Fed. Cir. 2001). Consequently, the court denies Smith & Nephew's motion for a new trial on the basis the exclusion of Judge Orrick's opinion.

4. Limitation of Dr. Manwaring's Testimony To His Expert Report

Smith & Nephew contends that Dr. Manwaring should have been permitted to testify at the trial about whether the Codman ME2¹³ emits ultraviolet photons and about testing conducted by Dr. Skromee to prove such emission. Smith & Nephew argues that this testimony was relevant to enable the jury to assess whether the Codman ME2 anticipates the asserted claims that have ultraviolet photon emissions as a limitation. However, Smith & Nephew did not produce Dr. Skromme's report until two days before Dr. Manwaring was scheduled to testify after the start of trial. Because Arthrocare was not afforded the opportunity to take discovery on the test results or to depose Dr. Skromme, the court excluded such evidence at trial, consistent with Rule 37(c)(1). The court, therefore, denies Smith & Nephew's motion for a new trial on the basis of the exclusion of Dr. Manwaring's testimony about ultraviolet photon emission testing.

5. Admission of Evidence of "Copying"

Smith & Nephew argues that admission of evidence of "copying" infected the entire trial and improperly inflamed the jury. In this regard, Smith & Nephew employees read the patents in suit and evaluated Arthrocare's patented products prior to

¹³The Codman ME2 is a commercial product embodied by the '158 or '138 prior art patent.

designing the accused products. (See D.I. 412 at 626-633; D.I. 415 at 1160-61; D.I. 417 at 1507-1508)

Prior to trial, in order to avoid any inferences of copying, Smith & Nephew made the strategic decision to withdraw its defense of obviousness and to stipulate to its knowledge of the patents in suit. Nevertheless, after a vigorous motion practice and lengthy discussions, the court concluded that the evidence was still relevant to the issue of inducing infringement. More specifically, in order to prove that Smith & Nephew induced infringement, it was Arthrocare's burden to prove that Smith & Nephew intended to encourage or to instruct its customers to directly infringe. Evidence of copying was appropriate circumstantial evidence going to intent; that is, if Smith & Nephew used Arthrocare's patented products as a template for its own, that would be circumstantial evidence that Smith & Nephew knew or should have known that its customers would directly infringe the patents in suit by using the Saphyre, ElectroBlade, and Control RF probes.¹⁴

At trial, Smith & Nephew presented evidence that it is customary and not inappropriate to evaluate competitors'

¹⁴It is ironic that Smith & Nephew, post-trial, argues that Arthrocare has not satisfied its burden of proving intent, based on the very evidence described above. See *supra*, Section IV, C, 5. Clearly, then, the fact of knowledge is not a sufficient basis for proving inducement and the evidence of intent is relevant.

products, and that it designed its own products without copying Arthrocare's patented products. (See D.I. 412 at 651-54; D.I. 414 at 951-53; D.I. 417 at 1507-08) Smith & Nephew was not prejudiced with respect to its ability to present the technical merits of its noninfringement and invalidity defenses to the jury. (See, e.g., D.I. 412 at 715-32; D.I. 414 at 805-822, 883-896, 962-970; D.I. 415 at 976-983; 999-1039; 1198-1227; D.I. 416 at 1288-1334; D.I. 417 at 883-896) Arthrocare, in turn, presented evidence to the contrary. (See, e.g., D.I. 411 at 376-500) Given the time spent on this noninfringement and invalidity evidence during the course of a nine-day jury trial, it cannot be said that disputed evidence relating to "copying" was disproportionately emphasized or time-consuming.

For all of these reasons, the court concludes that it was not error to admit evidence of "copying" and that such admission does not present grounds for a new trial.

6. Admission of Smith & Nephew Marketing Documents¹⁵

¹⁵Smith & Nephew failed to identify precisely which marketing documents that it believes were erroneously admitted. The court, consequently, is left to presume that Smith & Nephew is uniformly referring to any marketing type of document entered into evidence including the "Dyonics Control RF System" Sales Guide, "Saphyre Bipolar Ablation Probes" Sales Guide, "Instructions for Use Dyonics Series 7000 RF Arthroscopic Probe," "Competitive Selling Arthrocare," and the "Dyonics Series 9000 ElectrodBlade Resector." (See, e.g., PX 593, PX 390, PX 205, PX 324, PX 335)

Smith & Nephew claims that admission of its marketing documents, which appear to characterize Arthrocare's patent position as "strong," were irrelevant and inflammatory. Smith & Nephew contends that these documents could only be relevant to the issues of obviousness and its knowledge of the patents, but that neither were in dispute at trial.¹⁶ Moreover, Smith & Nephew argues that the opinions of its marketing and sales personnel regarding the strength of Arthrocare's patents are irrelevant.

The court finds that Smith & Nephew's marketing documents are relevant to the inducing infringement cause of action and, as such, that it did not err in admitting this evidence at trial. As the court discussed above in relation to evidence of "copying," Smith & Nephew's marketing documents are circumstantial evidence of Smith & Nephew's intent to induce infringement. These documents show how the alleged infringing products function and give instruction how to operate them. The court concludes that such information bears upon the manner in which Smith & Nephew encouraged its users to infringe Arthrocare's patents. Accordingly, the court denies Smith & Nephew's motion for a new trial on the basis the court's admission of Smith & Nephew's marketing documents.

¹⁶As mentioned above, Smith & Nephew withdrew its obviousness defense prior to trial and stipulated to its knowledge of the patents in suit during trial.

F. Smith & Nephew's Motion for A New Trial on the Basis of The Court's Jury Instructions

Smith & Nephew asserts that the court's instruction on infringement was "hopelessly confusing" for the jury when read in light of the court's claim construction for the "contact" limitation recited in claim 47 of the '536 patent and all of the asserted claims of the '592 patent.¹⁷ The court instructed the jury as follows concerning infringement:

In this case, Arthocare contends that Smith & Nephew's accused products and methods literally infringe the asserted claims. In order to prove that any one of the asserted claims is literally infringed, Arthocare must prove by a preponderance of the evidence that Smith & Nephew's accused products or methods include each and every limitation of that particular claim. In other words, you must compare the features of the accused products or methods with the limitations of each asserted claim in order to determine whether the accused products or methods include each and every limitation of an asserted claim.

With respect to the asserted claims of the '592 and '882 patents, the accused methods need not always practice the invention of any asserted method claim, so long as Arthocare has proven by a preponderance of the evidence that the accused methods operate in a way that meet each and every step of the method described in the claim some of the time.

(D.I. 418 at 1716) The court further instructed the jury as follows concerning the "contact" limitation:

The claim limitation the return electrode is not in contact with the body structure is clear -- the return electrode is not to contact the body at all during the performance of the claimed method. The claimed method

¹⁷Smith & Nephew objected to the these instruction at the charge conference. (See D.I. 416 at 1239-1241; D.I. 417 at 1469-1473)

does not contain any time limitations. Thus, the claimed method is performed when each of the three steps of the claim has been completed.

(Id. at 1718) Specifically, Smith & Nephew appears to argue that the source of the confusion lies in the juxtaposition of the language "at all" in the infringement instruction with the language "some of the time" in the claim construction instruction. Smith & Nephew argues that the jury may have read these instructions and thought that infringement occurred if the return electrode was not always in contact with the tissue.

Where the basis for seeking a new trial is an alleged error in the jury instructions, the error must be "so substantial that, viewed in light of the evidence in the case and the charge as a whole, the instruction was capable of confusing and thereby misleading the jury." Link v. Mercedes-Benz of North America, Inc., 788 F.2d 918, 922 (3d Cir. 1986). After reviewing the jury charge as a whole in light of the evidence presented in this case, the court cannot conclude that the jury instructions confused or misled the jury into believing that the accused products infringe the asserted claims if they are not in continual contact with tissue to warrant a new trial. The court instructed the jury separately regarding infringement and its claim construction, and both instructions properly stated the law. As well, the jury was asked to complete a special verdict form that explicitly separated the types of infringement, the

patents in suit, the asserted claims of each patent, and the accused infringing products. As a result of this separation, the jury was required to make finite determinations concerning whether a particular claim in a particular patent was infringed in a particular way by a particular product. Furthermore, the court finds no evidence to suggest that the jury was "hopelessly confused." The jury did not ask the court to clarify any of its instructions or pose any questions to the court during deliberations. The jury also did not incur any difficulty in completing the special verdict form as they entered responses in all required fields. (See D.I. 405) Therefore, the court denies Smith & Nephew's motion for a new trial on the basis of the court's jury instructions.

G. Smith & Nephew's Motion for A New Trial On the Grounds That the Validity of the Certificate of Correction Was Decided by the Jury

Smith & Nephew avers that the district court is better suited to decide the validity of the certificate of correction than a jury because such determination involves both a review of the factual determinations of a government agency and the legal decisions about the nature of the underlying mistake. The court disagrees. Smith & Nephew did not object to submitting this issue to the jury at any time during the trial or prior to the jury charge. Smith & Nephew appears now to raise this objection in the face of an unfavorable jury verdict. Even assuming,

arguendo, that the court did err in submitting this issue to the jury, the court, nevertheless, agrees with the jury's verdict that the certificate of correction is valid. The court, consequently, denies Smith & Nephew's motion for a new trial on the grounds that the validity of the certificate of correction was decided by the jury.

H. Smith & Nephew's Motion for A New Trial on the Basis of Arthrocare's Refusal to Limit the Issues at Bar

Smith & Nephew complains that it was allocated insufficient time to adequately try the number of issues presented by Arthrocare. As described by Smith & Nephew, Arthrocare asserted sixteen claims from three patents against three Smith & Nephew products.¹⁸ As a result, according to Smith & Nephew, the verdict form required the jury to make 107 separate factual findings, which it did in only 4.5 hours, thereby spending just over two minutes per finding.¹⁹

¹⁸In reality, Arthrocare asserted only six independent claims from three patents. All three patents involved the same technology and contained many identical claim limitations. Indeed, two of the patents share the same specification.

¹⁹Making such arguments is a dangerous business in Delaware, where so many patent cases are tried. The court could, for instance, cite to the case of KLA-Tencor Corporation v. ADE Corporation, Civ. No. 00-892-KAJ, where the jury returned a verdict in February 2004 on 17 issues in approximately 37 minutes, likewise spending just over two minutes per finding. The court suspects, however, that counsel for Smith & Nephew will not be complaining about that result, since it was favorable to its client in that case.

The court starts with the proposition, not really in issue here, that a district court has the inherent power to manage its docket. See, e.g., Duquesne Light Co. v. Westinghouse Elec. Corp., 66 F.3d 604, 609 (3d Cir. 1995). There are a finite number of trial hours in a calendar year. If the court failed to manage its caseload, parties would get to trial in four or five years, rather than 18 to 24 months. Therefore, in every civil case, the court determines the number of hours in which each party will be required to present its evidence and arguments to the jury. This decision is based on the court's calendar, its experience, and its review of the pretrial order submitted by the parties at bar. The number of hours allocated to the instant case was fair, based upon that review.²⁰ The record demonstrates that it was not lack of time that dictated the results in this case,²¹ but the evidence presented by Arthrocare. Accordingly, the court denies Smith & Nephew's motion for a new trial on the basis of Arthrocare's refusal to limit the issues at bar.

²⁰The court had assigned several more hours to this case, but postponed trial for a day (and, thus, reduced the total number of hours available for trial) at Smith & Nephew's request. In connection with this latter request, made the day before trial commenced, the court tried to, but could not, accommodate a further postponement of trial, based on a multitude of considerations, as discussed with counsel. (See D.I. 382, 390, 409)

²¹The court notes in this regard that Smith & Nephew's decision to dismiss its obviousness defense was as much related to evidentiary concerns as it was to trial management concerns. (See D.I. 409 at 16-17; see also *supra*, Section IV, E, 5)

I. Arthrocare's Motion for Entry of Judgment of No Inequitable Conduct and Smith & Nephew's Cross Motion to Strike Arthrocare's Motion for Entry of Judgment of No Inequitable Conduct²²

Smith & Nephew alleges that Arthocare committed inequitable conduct for each of the patents in suit: (1) during the prosecution of the '592 patent by informing the examiner that the '198 patent did not disclose the use of electrically conductive fluid and by not disclosing Judge Orrick's opinion; (2) during the reexamination of the '536 patent by failing to disclose Smith & Nephew's summary judgment briefs, Dr. Taylor's expert report, and the Roos declaration directed toward the issue of invalidity, and by engaging in improper "off-the-record" telephone conversations with the examiner regarding the merits of the '536 reexamination prior to the first substantive exam; and (3) during the process of obtaining the certificate of correction for the '882 patent by making two affirmative misrepresentations and by failing to explain how the so-called "correction" would broaden the scope of the claims.²³ Smith & Nephew charges that Mr. John Raffle,

²²Since the parties' cross motions are interrelated and focus of the issue of inequitable conduct, the court will consider their respective arguments together.

²³In granting the parties' request to file motions regarding inequitable conduct, the court indicated that such briefing was to be based upon the record established at trial. Therefore, to the extent that either party raised evidence not of record in their respective motions at bar, the court will ignore such evidence in deciding the instant motions. The court notes that Smith & Nephew seeks leave to depose the examiner responsible for

Arthrocare's in-house counsel responsible for prosecution of the '592 patent, misled the examiner concerning the use of electrically conductive fluid. Smith & Nephew claims that Mr. Raffle knew that claim 1 of the '198 patent recited "liquid to provide electrical conductance," but failed to call the examiner's attention to this limitation. In response to a February 29, 2000 office action issued by the examiner,²⁴ Mr. Raffle instead responded that "[t]he '198 patent never describes the use of 'electrically conductive fluid' during electrosurgery. The Roos '198 [p]atent only discloses the use of an unspecified 'washing liquid' that flows through the endoscope that houses the treatment and neutral electrodes. . . . The Roos '198 [p]atent does not state that the 'washing liquid' that is supplied to the region of the surgical site is electrically conductive fluid." (D.I. 428, ex. B at B23) Mr. Raffle also directed the examiner's attention to the '667 patent to substantiate his argument since this reference explains that "the device described in the

the reexamination of the '536 patent to determine the contents of his "off-the-record" conversation with Arthrocare's in-house counsel. The court denies this request.

²⁴The examiner stated:

Claims 80, 81, 83-85 . . . are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Roos The device includes a spaced return electrode as shown by Figure 1. A washing fluid passes through the axial lumen of the device. Since the return electrode is removed from the body structure, a conductive fluid must complete the current flow path.

(D.I. 428, ex. B at B17)

... '198 [p]atent[] did not work to cut tissue because the medium in contact with the electrodes was not electrically conductive." (Id. at B24) Smith & Nephew further argues that Arthrocare's inequitable conduct in connection with any one of the '592, '536, or '882 patents taints the enforceability of the remaining patents in suit. Arthocare rebuts these assertions in their entirety and moves the court to enter a judgment of no inequitable conduct.

Applicants for patents and their legal representatives have a duty of candor, good faith, and honesty in their dealings with the PTO. Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995); 37 C.F.R. § 1.56(a) (2003). This duty is predicated on the fact that "a patent is an exception to the general rule against monopolies and to the right of access to a free and open market." Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945). The duty of candor, good faith, and honesty includes the duty to submit truthful information and the duty to disclose to the PTO information known to the patent applicants or their attorneys which is material to the examination of the patent application. Elk Corp. of Dallas v. GAF Bldg. Materials Corp., 168 F.3d 28, 30 (Fed. Cir. 1999). A breach of this duty constitutes inequitable conduct. Mollins, 48 F.3d at 1178. If it is established that a patent applicant engaged in inequitable conduct with respect to one claim, then

the entire patent application is rendered unenforceable.

Kingsdown Med. Consultants v. Hollister Inc., 863 F.2d 867, 877 (Fed. Cir. 1988). A trial court may look beyond the final claims to their antecedents in determining inequitable conduct. Fox Indus., Inc. v. Structural Pres. Sys., Inc., 922 F.2d 801, 803 (Fed. Cir. 1990). "Claims are not born, and do not live, in isolation. Each is related to other claims, to the specification and drawings . . . [and] to earlier or later versions of itself in light of amendments made to it." Kingsdown, 863 F.2d at 874 (footnote omitted).

In order to establish unenforceability based on inequitable conduct, a defendant must establish by clear and convincing evidence that: (1) the omitted or false information was material to patentability of the invention; or (2) the applicant had knowledge of the existence and materiality of the information; and (3) the applicant intended to deceive the PTO. Mollins, 48 F.3d at 1178. A determination of inequitable conduct, therefore, entails a two step analysis. First, the court must determine whether the withheld information meets a threshold level of materiality. A reference is considered material if there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. Allied Colloids, Inc. v. American Cyanamid Co., 64 F.3d 1570, 1578 (Fed. Cir. 1995) (citations omitted). A

reference, however, does not have to render the claimed invention unpatentable or invalid to be material. See Merck v. Danbury Pharmacal, 873 F.2d 1418 (Fed. Cir. 1989).

After determining that the applicant withheld material information, the court must then decide whether the applicant acted with requisite level of intent to mislead the PTO. See Baxter Int'l, Inc. v. McGaw Inc., 149 F.3d 1321, 1327 (Fed. Cir. 1998). "Intent to deceive cannot be inferred solely from the fact that information was not disclosed; there must be a factual basis for finding a deceptive intent." Herbert v. Lisle Corp., 99 F.3d 1109, 1116 (Fed. Cir. 1996). That is, "the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive." Kingsdown, 863 F.2d at 876. A "smoking gun" is not required in order to establish an intent to deceive. See Merck, 873 F.2d at 1422. An inference of intent is warranted where a patent applicant knew or should have known that the withheld information would be material to the PTO's consideration of the patent application. Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256 (Fed. Cir. 1997).

Once materiality and intent to deceive have been established, the trial court must weigh them to determine whether the balance tips in favor of a conclusion of inequitable conduct.

N.V. Akzo v. E.I. DuPont de Nemours, 810 F.2d 1148, 1153 (Fed. Cir. 1988). The showing of intent can be proportionally less when balanced against high materiality. Id. In contrast, the showing of intent must be proportionally greater when balanced against low materiality. Id.

If an original patent is found unenforceable for inequitable conduct, descendent patents which are genealogically related to the original patent, such as continuations, continuations-in-part, or divisionals, may also be rendered unenforceable. See East Chicago Mach. Tool Corp. v. Stone Container Corp., 181 U.S.P.Q. 744, 748 (N.D. Ill. 1974). This theory of unenforceability has been termed "infectious unenforceability" by district courts and recognized by the Federal Circuit. See Baxter, 149 F.3d at 1327. It is premised on the guiding principle that "the duty of candor extends through the patent's entire prosecution history," and that a breach of the duty of candor "may render unenforceable all claims which eventually issue from the same or a related application." Fox, 922 F.2d at 803-04. Charges of infectious inequitable conduct are disfavored even more than charges of inequitable conduct.

Eaton Corp. v. Parker-Hannifin Corp., 2003 U.S. Dist. LEXIS 1014, *2 (D. Del. Jan. 24, 2003). To prove infectious unenforceability, an accused infringer must establish "inequitable conduct sufficient to hold at least one patent

unenforceable before [a court will] consider[] whether to hold **an** entire group of related patents unenforceable." Speedplay, Inc. v. Bebop Inc., 211 F.3d 1245, 1259 (Fed. Cir. 2000). If this threshold requirement is met, then the accused infringer must demonstrate an "immediate and necessary relation" between the alleged inequitable conduct and enforcement of the related patents. Ronald A. Katz Tech. Licensing, L.P. v. Verizon Communications Inc., 2002 U.S. Dist. LEXIS 12982, *7-8 (E.D. Pa. July 16, 2002) (internal citations omitted).

The court concludes that Arthocare did not commit inequitable conduct during the prosecution of the '592 patent, during the reexamination of the '536 patent, or in conjunction with the certificate of correction for the '882 patent. Considering the '592 patent, the court notes that the use of electrically conductive fluid is material to the patentability of the '592 invention given that it appears as a limitation in the asserted '592 patent claims. The court does not find that Mr. Raffle, however, intended to deceive the PTO concerning the '198 patent. Smith & Nephew presented no evidence of record to show that Mr. Raffle purposefully misrepresented material facts or submitted false material information about this prior art reference. Rather, the record shows that Mr. Raffle provided this prior art reference to the PTO for consideration during the prosecution of the '592 patent. (See D.I. 428, ex. B at B27)

The examiner was free to reach his own conclusions regarding the teachings contained in this reference.²⁵ (See id. at B23-26) Indeed, the Federal Circuit has opined that an examiner is free to accept or reject an inventor's interpretation of the teachings of a reference. Life Techs., Inc. V. Clontech Labs., Inc., 224 F.3d 1320, 1326 (Fed. Cir. 2000). Mr. Raffle's statements about electrically conductive fluid merely reflected his understanding of the '198 patent.

As to Judge Orrick's opinion, the court concludes yet again that it was not material to the patentability of the '592 patent. The opinion was preliminary in nature since it was issued pursuant to Arthrocure's motion for a preliminary injunction. It likewise did not directly address the anticipatory effects of the '198 patent on the application that was granted as the '592 patent. Rather, Judge Orrick found that the '198 patent raised substantial questions as to the validity of select claims of patents other than the '592 patent, namely, the '536 patent and the '281 patent.

Even assuming, arguendo, that Judge Orrick's opinion was material, Arthrocure complied with its duty of disclosure under the Manual of Patent Examining Procedure ("MPEP") Section 2001.06(c). This section states that

²⁵The examiner ultimately concluded that the '198 patent did not disclose electrically conducting fluid. (See id. at B40-41)

[w]here the subject matter for which a patent is being sought is or has been involved in litigation, the existence of such litigation and any other material information arising therefrom must be brought to the attention of the U.S. Patent and Trademark Office. . . . At a minimum, the applicant should call the attention of the Office to the litigation, the existence and the nature of any allegations relating to validity and/or 'fraud,' or 'inequitable conduct' relating to the original patent, and the nature of litigation material relating to these issues. Enough information should be submitted to clearly inform the Office of the nature of the issues so that the Office can intelligently evaluate the need for asking for further materials in the litigation.

MPEP § 2001.06(c) (2003). Arthocare submitted a list of documents from the Arthocare v. Ethicon, Inc. litigation to the PTO. This list included Judge Orrick's opinion. (See id. at B7, ¶40) The court cannot conclude that Arthocare intended to deceive the PTO concerning Judge Orrick's opinion given its compliance with Section 2001.06(c). Accordingly, the court grants Arthocare's motion for entry of judgment of no inequitable conduct as to the '592 patent and denies Smith & Nephew's cross motion to strike Arthocare's motion for entry of judgment of no inequitable conduct as to the '592 patent.

Turning to the '536 patent, the court finds that Arthocare did not intend to deceive the PTO concerning its suit against Smith & Nephew or conceal Smith & Nephew's primary arguments concerning validity and enforceability. In compliance with Section 2001.06(c), Arthocare notified the PTO about the litigation at bar and presented Smith & Nephew's invalidity

arguments in three separate communications, namely: (1) an Information Disclosure Statement dated October 12, 2001 disclosing Smith & Nephew's primary invalidity and unenforceability arguments; (2) a second Information Disclosure Statement dated June 6, 2002 disclosing Smith & Nephew's June 3, 2002 supplemental invalidity contentions in the form of Smith & Nephew's response to Arthrocare's contention interrogatories; and (3) a third Information Disclosure Statement dated December 19, 2002 attaching Smith & Nephew September 10, 2002 invalidity contentions. (See D.I. 428, ex. B at 76-87; 97-230; 290-341) Although these disclosures did not specifically include the summary judgment motions or expert reports in dispute, such documents were cumulative in nature with Smith & Nephew's invalidity contentions already before the PTO. Rule 56(b) states that "information is material to patentability in a reexamination proceeding when it is not cumulative to information already of record or being made of record in the reexamination proceeding." 37 C.R.F. §1.56 (2004). The Federal Circuit has also held that "[a] reference that is simply cumulative to other references does not meet the threshold of materiality that is predicate to a holding of inequitable conduct." Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1582 (Fed. Cir. 1991) (citing Halliburton Co. v. Schlumberger Tech. Corp., 925 F.2d 1435, 1440 (Fed. Cir. 1991)). In addition, the court notes

that these documents were designated "highly confidential" and were subject to the parties' stipulated protective order. This protective order limited the use of "highly confidential" information to persons or entities "to whom such information is disclosed solely for the purposes of this action, and not for any other action or for any business, patent prosecution, licensing, competitive, or governmental purpose or function, and such information shall not be disclosed to anyone except as provided in this [p]rotective [o]rder." (D.I. 40 at ¶6) The in-house corporate counsel who prosecuted the '536 patent during reexamination (i.e., Mr. Raffle and Mr. Sanjay Bagade), consequently, were not privy to "highly confidential" documents. The court, therefore, reasons that Arthrocare's in-house counsel did not intend to deceive the PTO about Smith & Nephew's summary judgment motions and expert reports because they likely were unaware of the existence of these documents.

As to Arthrocare's "off-the record" conversations with the examiner during the '536 reexamination prior to the first office action,²⁶ there is no evidence of record to suggest that Arthrocare's in-house counsel violated 37 C.R.F. § 1.56 or MPEP § 2281. Interviews about the patentability of claims involved in an ex parte reexamination proceeding ordinarily are not conducted

²⁶The examiner issued the first office action on September 24, 2002.

prior to the first office action. See 37 C.R.F. § 1.56 (2004); see also MPEP § 2281 (2001). However, interviews are "permitted where the examiner initiates the interview for the purpose of providing an amendment to make the claims patentable and the patent owner's role is passive. The patent owner's role . . . is limited to agreeing with the change or not." Id. Additionally, 37 C.R.F. § 1.56 and MPEP § 2281 require the patent holder to file a written statement of the substance of the interview with the PTO. In accordance with these rules, Mr. Bagade submitted a statement on December 19, 2002 to summarize various communications with the examiner. While the exact number of conversations between Arthrocare's in-house counsel and the examiner and the dates of such conversations are not clear from the contents of Mr. Bagade's statement, it is evident that at least one occurred prior to the first office action because Mr. Bagade stated that the examiner contacted him in May 2002. (See D.I. 462, ex. B at 228-230) This interview, nevertheless, was consistent with the requirements of MPEP § 2281. That is, the examiner contacted Mr. Bagade for purposes of discussing an amendment to claim 1 of the '536 patent, and Mr. Bagade responded by not agreeing to the amendment. (See id.)

Even though the court cannot identify with certainty the time frames for the remaining interviews of record, the court concludes that the record does not suggest that Mr. Raffle caused

the examiner to "parrot back, verbatim" the arguments that he made with respect to the '198 patent during the earlier prosecution of the '592 patent as alleged by Smith & Nephew, despite his discussions with the examiner about the '198 patent, the '667 patent, and Judge Orrick's opinion.²⁷ Under patent office rules, a patent examiner is charged with a duty to independently conduct a thorough examination.

On taking up an application for examination or a patent in a reexamination proceeding, the examiner shall make a thorough study thereof and shall make a thorough investigation of the available prior art relating to the subject matter of the claimed invention. The examination shall be complete with respect both to compliance of the application or patent under reexamination with the applicable statutes and rules and to the patentability of the invention as claimed, as well as with respect to matters of form, unless otherwise indicated.

37 C.R.F. §1.104(a)(1) (2004). The Federal Circuit "presumes that the Patent Office complies with its own rules, a presumption overcome only upon presentation of contrary evidence." Genzyme Corp. v. Transkaryotic Therapies, Inc., 346 F.3d 1094, 1103 (Fed. Cir.) (citing Rite Hite Corp. v. Kelley Co., Inc., 819 F.2d 1120, 1123 (Fed. Cir. 1987)). In line with this duty, the examiner placed his initials next to the '198 patent on the Form PTO-1449, indicating that he considered the patent. The examiner confirmed

²⁷Additional communications of record entailed procedural concerns, such as the status of the reexamination proceedings, filing of information disclosure statements, and an estimate of when the PTO would provide the first office action.

this review in a November 15, 2002 office action, stating that he engaged in "careful[] consideration and review of the Roos '198 patent." (PX 7 at 214) Therefore, without evidence of indiscretion during the '536 reexamination proceeding, the court finds that Smith & Nephew's allegations regarding inequitable conduct based on off-the-record conversations to be without merit. Consequently, the court grants Arthrocare's motion for entry of judgment of no inequitable conduct as to the '536 patent and denies Smith & Nephew's cross motion to strike Arthrocare's motion for entry of judgment of no inequitable conduct as to the '536 patent.

Focusing on the '882 patent, the court finds no evidence in the record to substantiate Smith & Nephew's allegations that Mr. Raffle intentionally misled the PTO when he asserted that he amended all claims to replace the term "active electrode" with "electrode terminal" or when he presented an antecedent basis argument as grounds to amend application claim 23 (i.e., issued claim 1) but did not point out other instances of improper antecedent basis within the claim set. Mr. Raffle filed a supplemental amendment during the prosecution of the '882 patent to change "active electrode" to "electrode terminal" and "electrically conducting liquid" to "electrically conducting

fluid.”²⁸ (See DTX 306 at C2-C12) He missed one correction of “active electrode” in application claim 23 and one instance of the same correction in application claim 52. Recognizing these mistakes after reviewing the ‘882 patent on the day it issued, Mr. Raffle filed a request for certificate of correction the following day. (See 1527, DTX 306 at C13-C15) In his request, Mr. Raffle explained that he mistakenly forgot to replace the term “active electrode” with “electrode terminal” in one place in application claim 23 and that such failure potentially created an antecedent basis problem. (See DTX 306 at C13) Given this sequence of events, the court concludes that Mr. Raffle made honest mistakes in amending the claims; he did not craft claims to read on Ethicon’s products in order to file an infringement action against Ethicon. The court, consequently, grants Arthrocure’s motion for entry of judgment of no inequitable conduct as to the ‘882 patent and denies Smith & Nephew’s cross motion to strike Arthrocure’s motion for entry of judgment of no inequitable conduct as to the ‘882 patent.

Finally, because the court has not found Arthrocure liable for inequitable conduct with respect to any of the individual patents in suit, the court declines to hold them collectively unenforceable based upon an alleged pattern of inequitable

²⁸Mr. Raffle replaced seventeen of the nineteen occurrences of the term “active electrode,” including three in application claim 23 and two in application claim 52.

conduct. Even if the court had found just one patent invalid on inequitable conduct grounds, the court is not convinced that Smith & Nephew would be able to show an "immediate and necessary relation" between the inequitable conduct associated with that one patent and the enforcement of the other two patents. To establish the requisite relatedness, Smith & Nephew relies on the fact that the three patents in suit share the same inventors, concern the same electrosurgical system, have been licensed together, and were asserted concurrently in the instant litigation. Nevertheless, this court agrees with the Eastern District of Pennsylvania's holding that "'[m]ere relatedness of subject matter' is insufficient to establish this [immediate and necessary] relationship." Id. (citing Consol. Aluminum Corp. v. Foseco Int'l Ltd., 910 F.2d 804, 810-811 (Fed. Cir. 1990)). In cases where courts found infectious unenforceability, there was greater connection between the act that triggered the inequitable conduct finding and the other patents in suit than in the case at bar. For example, in Consol. Aluminum Corp. 910 F.2d 804, the Federal Circuit held that the intentional fabrication of a fictitious best mode in one patent rendered three other patents with intertwined prosecution histories, two of which were continuations-in-part of the third, unenforceable. The court, therefore, grants Arthrocare's motion for entry of judgment of no inequitable conduct and denies Smith & Nephew's cross motion to

strike Arthrocare's motion for entry of judgment of no inequitable conduct on infectious unenforceability grounds.

J. Arthrocare's Motion for a Permanent Injunction

Arthrocare moves for entry of a permanent injunction to enjoin Smith & Nephew from directly infringing, contributing to the infringement, and inducing the infringement of the '536, '592, or '882 patents (1) by making, using, offering to sell, selling, marketing, advertising, or promoting in the United States or importing into the United States all models of the Saphyre, ElectroBlade, and Control RF products until the expiration of the patents in suit; and (2) by instructing, training, or otherwise actively encouraging others in the United States to use all models of the Saphyre, ElectroBlade, and Control RF products until the expiration of the patents in suit.

The framers of the Constitution of the United States recognized that a patentee has the right to exclude others from practicing a patented invention. As a result of this belief, the framers adopted Clause 8 of Section 8, Article I which states: "The Congress shall have power . . . to promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." U.S. Const. art. I, § 8. Congress used their power to enact 35 U.S.C. § 283. This provision of law authorizes a court to "grant injunctions in accordance with the

principles of equity to prevent the violation of any right secured by patent, on such terms as the [c]ourt deems reasonable." 35 U.S.C. § 283.

In a patent infringement suit, a district court may grant a preliminary injunction pending trial or a permanent injunction "after a full determination on the merits." High Tech. Med. Instr., Inc. v. New Image Indus., Inc., 49 F.3d 1551, 1554 (Fed. Cir. 1995). Indeed, the Federal Circuit has indicated that once a finding of infringement has been made, then an injunction should issue absent a sufficient reason for denying it. Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 1247 (Fed. Cir. 1989). Courts, therefore, are given wide latitude in framing injunctive relief. KSM Fastening Sys., Inc. v. H.A. Jones Co., 776 F.2d 1522, 1527 (Fed. Cir. 1985). Nonetheless, consistent with the equitable nature of a permanent injunction, the court "must consider all circumstances, including the adequacy of the legal remedy, irreparable injury, whether the public interest would be served, and the hardship on the parties and third parties. E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co., 659 F. Supp. 92, 94 (D. Del. 1987). Additionally, Rule 65(d) of the Federal Rules of Civil Procedure requires an injunction to "set forth the reasons for its issuance, be specific in its terms, and shall describe in reasonable detail, and not by reference to the complaint or other document, the act

or acts sought to be restrained; and is binding only upon the parties to the action." Fed. R. Civ. P. 65(d).

In the instant case, the court finds Arthocare will suffer irreparable harm without a permanent injunction to prevent Smith & Nephew from practicing its patented inventions. As best stated by the Federal Circuit in H.H. Robertson Co. v. United Steel Deck, Inc., 820 F.2d 384 (Fed. Cir. 1987):

In matters involving patent rights, irreparable harm has been presumed when a clear showing has been made of patent validity and infringement . . . The nature of the patent grant thus weighs against holding that monetary damages will always suffice to make the patentee whole, for the principal value of a patent is its statutory right to exclude.

Id. at 390.

Additionally, the public interest in preserving incentives to advance science and useful arts favors entry of an injunction to bar any further infringement by Smith & Nephew. The court recognizes that intellectual property law is premised on the desire to give inventors an incentive to invent and to reap the benefits of their labor. To this end, the Federal Circuit has previously noted that

[o]ne of those benefits is the right to prevent others from practicing what they have invented. Otherwise, if inventors cannot depend on their patents to exclude others, we fear that research and development budgets in the science and technology based industries would shrink, resulting in the public no longer benefitting from the labors of these talented people.

E.I. DuPont de Nemours v. Polaroid Graphics Imaging, Inc., 706 F. Supp. 1135, 1146 (D. Del. 1989). Under the facts at bar, Arthrocare created the market for electrosurgery probes by launching its first bipolar radio frequency ablation product for arthroscopic surgery in 1995. (See PX 450 at 3) Smith & Nephew later joined this market. (See PX 593 at 24, 39)

Finally, the court notes that removing the Saphyre, ElectroBlade, and Control RF probes from the stream of commerce will not harm or cause hardship to the public since Arthrocare, along with several other suppliers like Mitek and Stryker, offer alternative viable probes. As well, Smith & Nephew has already pulled the Control RF product from the market and only just recently launched the ElectroBlade and Saphyre products. The fact that Smith & Nephew may suffer a loss in revenue is not of concern. Indeed, the Federal Circuit has commented that just because an injunction might put an infringer out of business does not justify denying it. See Windsurfing Int'l, Inc. v. AMF, Inc., 782 F.2d 995, 1003 (Fed. Cir. 1986). "One who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected." Id. Therefore, concluding that all relevant factors weigh in favor of granting a permanent

injunction, the court grants Arthrocare's motion for a permanent injunction.²⁹

V. CONCLUSION

For the reasons stated, the court denies Smith & Nephew's motion for judgment as a matter of law, motion for a new trial, and motion to strike Arthrocare's motion for entry of judgment of no inequitable conduct. The court also denies Smith & Nephew's motion to modify the protective order. The court grants Arthrocare's motion for entry of judgment of no inequitable conduct and motion for entry of a permanent injunction. An order shall issue.

²⁹The court notes that Smith & Nephew's antitrust counterclaims are no longer pending before the court and will not be adjudicated in phase two. The court granted Arthrocare's motion to dismiss Smith & Nephew's antitrust counterclaims in a separately issued memorandum opinion. For this reason, the court concludes that it is not premature to issue a permanent injunction at this time.